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ANDHealth
Australia's National Digital Health Initiative

REGULATION OF SOFTWARE, INCLUDING SOFTWARE AS A MEDICAL DEVICE (SAMD)

Feedback to the TGA's Consultation Document | March 2019

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Feedback to the TGA's Consultation

Regulation of Software, including Software as a Medical Device (SaMD)

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BACKGROUND

TGA's Proposed Regulatory Reforms and Request for Feedback

In February 2019, the TGA released the consultation document Regulation of software, including Software as a Medical Device (SaMD) which addresses proposed changes to the regulatory environment for medical device software, including software that functions as a medical device in its own right (SaMD). The proposed reforms seek to improve the regulation of software, including SaMD, and wherever possible, harmonise with international best practice.

The TGA identifies three key issues regarding the current regulation of software, including SaMD, under the medical device regulatory framework in Australia:

- Classification rules (under current regulations) do not adequately consider the potential for SaMD products to cause harm to patients.
- Software can now be downloaded by the user directly from the publisher, without the need for an importer or retailer. This means that there is no entity in Australia that is monitoring the safety and performance of directly-imported SaMD and that there is no-one accountable to the regulator for post-market actions.
- Lack of clarity in the regulatory requirements for demonstrating safety, quality and efficacy.

The TGA's proposed changes are as follows:

1. Ensuring the classification rules for medical devices will appropriately classify SaMD products according to the potential harm they could cause to patients (**Proposed Change 1: Classification rule changes**)
2. Excluding SaMD products from the personal importation provisions in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) so that SaMD products will be required to be included in the ARTG and will require an Australian sponsor (**Proposed Change 2: Requiring SaMD to be included in the ARTG**)
3. Ensuring the essential principles for medical devices include clear and transparent requirements for demonstrating the safety and performance of SaMD and other regulated software (**Proposed Change 3: Changes to the essential principles**)

OVERVIEW OF ANDHEALTH'S POSITION ON DIGITAL HEALTH REGULATION, INCLUDING SAMD

As a nascent industry, digital health regulation requires regulatory flexibility and an open dialogue as trends and new technologies emerge. Whilst an approach which leverages existing terms and legislative instruments may be expeditious in the short term, a longer-term view will require the ability to adapt to technologies which may not "fit" within traditional terminology.

We refer the TGA to the recent report *Digital Health: Creating a New Growth Industry for Australia* published by ANDHealth after significant and broad reaching consultation across the many sectors which contribute to digital health. This report outlines key concerns and recommendations of industry participants as it relates to regulation, alongside similar concerns and recommendations encompassing technology development, investment and implementation in digital health. The section of this report that relates to regulation is appended for ease of reference.

ANDHealth as an organisation advocates for appropriate regulatory oversight of digital health technologies, based on the premise that regulation offers a number of critical safeguards surrounding safety, quality and efficacy for both users and customers (i.e. if a health claim is made, that claim should be based on verifiable, robust evidence), and improves the commercial potential of new innovations via contributing to a defensible competitive position and providing third party authentication of clinical evidence/ claims and product quality. In addition, the enemy of commercialisation and investment is uncertainty. Thus, the clarification of regulation supports commercialisation by providing certainty of the regulatory pathway, and clarity of the regulatory value inflection points that may occur.

As such, ANDHealth is positive towards the changes proposed by the TGA, however would like to see further exploration of a number of items either not fully defined or not explicitly referred to, in the consultation document. These items include:

- Harmonisation with international regulatory regimes relating to digital health products across medical regulation and data privacy and security;
- Recognition of the role of iterative development and ongoing product evolution specific to digital health products and clarity regarding when new approvals are required (which may include implementation of a

regime similar to the FDA Pre-Certification Program for digital health companies, whereby approved developers can access significantly expedited pathways through the approval process[1]);

- Defined and reliable timeframes within which regulatory clearances and approvals take place, allowing companies, investors and key partners/ customers/ stakeholders to be able to adequately plan for and roll out deployments of software-based health products;
- Definition of key terms used in the consultation document to avoid misunderstanding and to provide adequate clarity for developers seeking to comply with the new classifications and requirements; and
- Further clarification of the transition period, an understanding of the timeframes companies may face when seeking to gain regulatory approval for both existing and new SaMD products and consideration to the level of support required of the TGA in this transition period.

In addition, there are a number of areas within the digital health sector which may require further exploration and consultation. The first is consideration of the additional regulatory burden generated by these changes which may borne by pharmaceutical and medical device companies that develop digital/ software-based applications as companion products around their core product offerings. Consideration for whether this will disincentivise such manufacturers from pursuing the additional healthcare gains potentially delivered via these companion offerings.

Secondly is the consideration as to whether a 'device lens' is the appropriate viewpoint for long term regulatory oversight in digital health. In recent years, the FDA has provided clearances for software applications used as a therapy ('digital therapeutics') that have evidence supporting specific clinical claims and outcomes, are supported by randomised clinical trial results and can be prescribed under the care of a health professional.

These technologies provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings. Examples include prescription cognitive behavioural therapy for substance use disorders for improving abstinence (reSET® and reSET-O® by Pear Therapeutics®[2]) and type 2 diabetes self-management delivered as prescription with insulin dosing (Bluestar® Rx by WellDoc®[3]) or without insulin dosage and available over-the-counter (BlueStar®[3]).

Presently in Australia, prescription medicine that is prescribed by a registered health care practitioner follows a different regulatory path to medical devices. Although similar in their risk-based approach, prescribed medicines have different supportive data requirements and evaluation steps to medical devices, including SaMD. While it is still unclear how 'digital therapeutics' will precisely fit in the Australian healthcare ecosystem (such as behaving as a prescribed therapeutic or as traditional medical device), ANDHealth advocates for the best regulatory environment that fosters innovation domestically and increases the availability of products that benefit the health of Australians and people of other nations, whilst providing the right level of regulatory rigor for safety, quality and efficacy.

Relevantly, the proposed classifications included "software that provides therapy through direct interaction" (Proposed Change 1). This would appear to capture most 'digital therapeutics'. However, such software, perhaps operable on a variety of hardware platforms or in the cloud, may not meet the underlying hurdle of falling within the definition of medical device in s41BD of the *Therapeutic Goods Act 1989*.

An alternative to classifying these types of products as "software as a medical device" is to view them as medical services delivered digitally. Given the global acceptance of Software as a Service businesses and business models, consultation around the concept of what ANDHealth would term Medical Software as a Service (MedSaaS), and whether a more appropriate regulatory route for certain types of digital health companies would fall into medical services regulation is an issue demanding of further discussion and consultation. ANDHealth notes that this would also provide a clearer pathway to reimbursement, and therefore a stronger environment for both commercialisation, and access to world class digital health products to improve the health of all Australians.

[1] *Pre certification Program (FDA) and real world data: The premise behind the US Food and Drug Administration's (FDA) current pilot of the Digital Health Software Pre-Certification (Pre-Cert) Program is that the FDA certifies the company that creates the product, and following this company-wide certification, new products released by the company are deemed "pre-certified" and as such benefit from an expedited approval pathway. Once approved, products then go on to meet usual post-market monitoring and reporting requirements. The FDA believes the pilot can be used to inform the development of a new regulatory model that enables the least burdensome regulatory oversight with a tailored, pragmatic approach that does not inhibit access to technology for patients.*

[2] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628091.htm

[3] https://www.accessdata.fda.gov/cdrh_docs/pdf16/k162532.pdf

Finally, ANDHealth and its stakeholders have identified that the vast majority of funding for regulation is generated through fees charged under cost recovery arrangements leaving limited resources available for industry education and engagement. Should the changes proposed in the consultation document be implemented, ANDHealth would support any request for additional funding for the TGA to enable it to undertake a significant program of industry education and engagement to ensure industry participants are fully aware of the processes, timelines, expectations and costs of regulatory approval with respect to digital health products.

PROPOSED CHANGE 1: CLASSIFICATION RULE CHANGES

Summary of Proposed Change

Under the current TGA framework, only Regulation 3.3 (5) includes specific rules for classifying software:

> 3.3 Principle for applying the classification rules
> (5) If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.

The TGA's concern is that this existing rule does not capture software that is not associated with a medical device and is therefore not applicable to software as a medical device (SaMD). As a result, all SaMD, when correctly classified under the current framework, is only Class I. Devices of this classification do not require any third-party oversight of their design, development or performance before, or while, they are included in the ARTG.

To counter this Class I classification of all SaMD, the TGA proposes the following:

Software that processes data (e.g. – images, sensor data, big data) to provide information for diagnosing a disease or condition and that is intended to:

- Make a direct diagnosis (e.g. – self testing, emergency situation, rural or remote medicine) for:
  - a critical situation where the disease or condition is fatal or debilitating in a short timeframe, or poses a risk to public health, or a serious situation where the disease or condition is not life threatening but may cause a serious deterioration in a person's state of health if not identified. The device is Class III.
  - any other situation. The device is Class IIa.
- Screen patients to determine the need for further assessment for:
  - a disease or condition that is fatal or debilitating in a short timeframe, or that poses a risk to public health. The device is Class III.
  - a disease or condition that is not life threatening but may cause a serious deterioration in a person's state of health if not identified. The device is Class IIb.
  - any other situation. The device is Class IIa.
- Aid a clinician in making a diagnosis. The device is Class IIa.

Software that processes data to provide information for treatment or intervention in a disease or condition and that is intended to:

- Specify a treatment or intervention that will be administered without further consideration (e.g. – the patient will inject the amount of insulin calculated) where:
  - the treatment or intervention, or its absence, could result in death or debilitation. The device is Class III.
  - the treatment or intervention, or its absence, could be harmful. The device is Class IIb.
  - the treatment or intervention, or its absence, is unlikely to cause harm. The device is Class IIa.
- Recommend a treatment or intervention for a clinician to decide and administer. The device is Class IIa.

Software that provides therapy through direct interaction with a patient where:

- The software directs patient activity based on input from the patient and could result in patient harm (e.g. – directing a recovering heart patient to undertake activity that is too vigorous). The device is Class IIb.
- The software directs patient activity based on input from the patient and the activity is unlikely to cause harm. The device is Class IIa.
- The software directs patient activity based on a non-interactive intervention. The device is Class I.

ANDHealth Response

CHANGE 1: CLASSIFICATION OF SaMD	
Are the proposed changes supported?	Yes, the general principles of reclassification are supported by ANDHealth.
Benefits of the proposed changes	• These changes address prior feedback from stakeholders that the current status quo is unclear with respect to the need for regulatory approvals/ clearances for digital health technologies. • Increased certainty around requirements removes risk and uncertainty for all parties involved in development, commercialisation and implementation. • Regulation and regulatory approvals should be viewed as a competitive advantage for digital health innovators. • Certainty of regulatory requirements removes uncertainty and risk, and provides greater clarity around value inflection points for investors. • Regulatory approvals provide comfort to both end users and customers of the validity (evidence-base) and quality of digital health technologies.
Disadvantages of the proposed changes	• New SaMD products that would previously be classified as Class I would be elevated to Class IIa, IIb and III medical devices subject to third party oversight. • Where such products are already in development/ commercialisation, this change may require repetition of certain aspects of development and additional funding to reach market. • Existing SaMD products would need to be reclassified and subject to a transition period. This will almost certainly trigger costs for existing technology companies who have not factored in the need for TGA standard regulatory processes (including clinical trials). • It is difficult to quantify the impact on such companies in terms of cost, time and loss of existing customers. This will also likely impact the valuation of these companies where they have previously raised capital on the premise that regulatory approvals were not required. • A number of terms in the proposed change will require further clarification in order for companies to easily understand their obligations (see Overview of ANDHealth's Position). • Inclusion of 'digital therapeutics' as a class of medical device may introduce confusion because "software that provides therapy through direct interaction" may not fall within the definition of medical device used in the *Therapeutic Goods Act 1989*.
Suggested alternatives/ Areas for further TGA consultation & consideration	• It is essential to ensure that Australian SaMD products and services not only meet regulatory requirements within the Australian market but also have the ability to align to international standards and to enable export potential for key markets such as Europe (through the EMA) and the US (through the FDA). • As such, all proposed changes to the Australian regulatory environment should seek to achieve international harmonisation wherever possible. • The transition period outlined by the TGA will be critical. Further clarity regarding the transition period and any exemptions is required. • A concerted effort should be made to quantify the number of companies and technologies likely to be affected, and the economic cost to both those companies and the broader healthcare system if delivery of technologies (already in use in clinical care) need to be halted whilst regulatory approvals are gained. • Following the reclassification of SaMD products to higher levels of medical device classification, Clinical Evidence Guidelines for Medical Devices may now become relevant for newly classified Class II and higher digital health products. • This may mean that Part 1. Section 2: Clinical Evidence may now apply to SaMD products to "demonstrate compliance with the essential principles to establish the safety and performance of the medical device for its intended purpose". • As such, review of the clinical evidence requirements to suit SaMD products, or establishment of clinical evidence requirements specific to SaMD products, may be required. • An alternative to classifying these types of products as "software as a medical device" is to view them as medical services delivered digitally. Given the global acceptance of

	Software as a Service businesses and business models, consultation around the concept of what ANDHealth would term Medical Software as a Service (MedSaaS), and whether a more appropriate regulatory route for certain types of digital health companies would fall into medical services regulation is an issue demanding of further discussion and consultation. ANDHealth notes that this would also provide a clearer pathway to reimbursement, and therefore a stronger environment for both commercialisation, and access to world class digital health products to improve the health of all Australians.
Organisational arrangements needed to meet the proposed changes	Organisational arrangements needed to make the proposed changes are variable and highly dependent upon: • The type and structure of the company; • The type of technology requiring initial regulatory assessment (or reclassification); • The capabilities of in-house regulatory counsel; and • The availability of specific industry regulatory consultants who are up to speed and able to service industry demand.
Financial impact (both costs and savings) with a breakdown (if possible) of proposed changes	• The financial impact of these changes will be highly variable, depending on the type and structure of the company, the technology to be regulated (or re-classified), along with the availability of regulatory support, including in-house or through an external supplier. • SaMD previously classified as Class I and elevated to Class IIa, IIb and III medical devices subject to third party oversight would likely impact the valuation of these companies where they have previously raised capital on the premise that regulatory approvals were not required.
Period needed to implement the proposed changes.	• The period needed to implement these changes will be dependent on the type and structure of the company, the type of regulated technology, along with the availability and capability of regulatory support. • Consideration as to the level of support required of the TGA in provision of pre-submission consultations and the support of education and support resources during transition period is suggested as this level of support will impact the time organisations need to implement the proposed changes

PROPOSED CHANGE 2: REQUIRING SAMD TO BE INCLUDED IN THE ARTG

Summary of Proposed Change

The TGA has proposed that the Therapeutic Goods (Medical Devices) Regulations 2002 be amended so that all SaMD products are required to be included in the Australian Register of Therapeutic Goods (ARTG) by excluding them from the provisions for personal importation. This change would mean that all SaMD products would require an Australian sponsor before they can be supplied in Australia, including through internet download.

This recommendation is aimed at ensuring that there is an Australian entity responsible for monitoring the product and reporting to the TGA. It would also mean that SaMD products developed and distributed from overseas will not be able to bypass the regulatory requirements for medical devices in Australia, for example compliance with the essential principles.

ANDHealth Response

CHANGE 2: REQUIRING SaMD TO BE INCLUDED IN THE ARTG	
Are the proposed changes supported?	Yes
Benefits of the proposed changes	The supply (especially via download) of digital health products which cannot point to robust evidence to support their claims is a known issue. This change will improve visibility of SaMD products being supplied in Australia since all would be included in the ARTG.

	In addition, it removes a loophole for international companies and developers to bypass the strengthened regulation as outlined in Change 1.
Disadvantages of the proposed changes	Australia is a relatively small healthcare market compared to the global healthcare market. It is possible that international manufactures of SaMD may not service the Australian market if significant regulatory hurdles are imposed, or that patients and the Australian healthcare system may bear the cost of incorporating a local sponsor into the supply chain.
Suggested alternatives/ Areas for further TGA consultation & consideration	Although changes to classifications and listing SaMD products on the ARTG will go some way to providing assurances for Australian health consumers, consideration should be given as to whether this can be extended to form a curated library of evidence based SaMD products, i.e. a 'heart tick of approval' style system for consumer facing applications to better inform Australian consumers of the validity of the applications they are purchasing and using.
Organisational arrangements needed to meet the proposed changes	Organisational arrangements needed to make the proposed changes are variable and highly dependent upon: • The type and structure of the company; • The type of technology requiring initial regulatory assessment (or reclassification); • The capabilities of in-house regulatory counsel; • The availability of specific industry regulatory consultants who are up to speed and able to service industry demand; and • Relationships between international developers and local sponsors. along with existing relationships with local sponsors.
Financial impact (both costs and savings) with a breakdown (if possible) of proposed changes	• For overseas companies, the financial impact of these proposed changes will vary depending upon the overseas company's structure, technology to be regulated and arrangements with local sponsors. Overseas developers may elect to pass the cost of incorporating a local sponsor into the supply chain on to patients and the broader Australian healthcare system, which may ultimately limit access to technologies that benefit the health of Australians. For local developers, the financial impact of these changes will be highly variable, depending on the type and structure of the company, the technology to be regulated (or re-classified), along with the availability of regulatory support, including in-house or through an external supplier.
Period needed to implement the proposed changes.	• The period needed to implement these changes will be dependent on the type and structure of the company, the type of regulated technology, along with the availability and capability of regulatory support. • Consideration as to the level of support required of the TGA in provision of pre-submission consultations and the support of education and support resources during transition period is suggested as this level of support will impact the time organisations need to implement the proposed changes.

PROPOSED CHANGE 3: CHANGES TO THE ESSENTIAL PRINCIPLES

Summary of Proposed Change

The requirements for the safety and performance of medical devices are expressed under the current regulatory framework as the 'essential principles'. These essential principles do not specify particulars to which standards must be complied with or what testing must be undertaken. Instead, they allow flexibility to regulate all medical devices, including new technologies. The TGA has identified that current essential principles do not include any explicit mention of software, which makes it unclear for companies to determine what is required to comply with Australian legislation.

The TGA proposes to add the following points of clarification into the essential principles:

- The features, capabilities and risks of the computing platform be taken into account during design and manufacturing
- The cyber security risks associated with network connectivity be minimised
- That software be designed and produced using best practice software engineering principles
- That medical devices indicate when critical features and connections are or are not enabled, and provide appropriate alarms

- Best practice cyber security principles be used regarding the risk of unauthorised access to the device
- Medical devices be designed to facilitate software updates, and information about the clinical risk of an update is provided to the user
- That requirements relating to the computer platform, operating system, accessories and network security be provided in the instructions for use

ANDHealth Response

CHANGE 3: CHANGES TO THE ESSENTIAL PRINCIPLES	
Are the proposed changes supported?	ANDHealth agree that the regulatory framework around who can access the data and under what conditions and for what purposes should ideally be considered in the essential principles and be framed to enable innovation whilst protecting consumer interest and engendering consumer trust.
Benefits of the proposed changes	• The proposed changes provide appropriate context to the essential principles in relation to best practice software development and cyber security. ANDHealth would expect that companies seeking to commercialise evidence-based digital health products would be seeking to apply these practices in their operations. • The changes support a responsible approach to the development of SaMD products, including ensuring data privacy and security concerns are addressed and provision of appropriate information to end users. • ANDHealth supports the application of appropriate quality management and software development practices, including ISO 62304 and ISO 13485. In addition, relevant security certifications should be sought, and appropriate data privacy and protection standards incorporated. • Companies seeking to commercialise globally should already be operating to such standards. As such ANDHealth considers the formalisation of expectations around these aspects of SaMD development to be positive. • The safe and efficacious use of SaMD products relies upon the provision of clear and easily understandable patient and user information, including with respect to risks.
Disadvantages of the proposed changes	Where digital products are delivered as companion products to more traditional devices and therapeutics, consideration should be given to the regulatory burden borne by the manufacturers, and ensuring that the increased burden does not dissuade the development and deployment of products which amplify positive health outcomes.
Suggested alternatives/ Areas for further TGA consultation & consideration	• ANDHealth notes that software updates and upgrades are an ongoing reality for those organisations developing SaMD products. • The extent to which an update/ upgrade is considered a component of the existing product, versus an update/ upgrade that may trigger the need for new regulatory clearance, is not contemplated in the consultation document. • Clarification of how updates/ upgrades are managed, and in what instances new regulatory clearances are required is recommended.
Organisational arrangements needed to meet the proposed changes	Organisational arrangements needed to make the proposed changes are variable and highly dependent upon: • The type and structure of the company; • The type of technology requiring regulatory assessment; • The capabilities of in-house technology, regulatory, quality and compliance teams; • The availability of specific industry consultants who are up to speed and able to service industry demand; and • Access to technology focused platforms and advisors which can support development in compliant environments.
Financial impact (both costs and savings) with a breakdown (if possible) of proposed changes	The financial impact of these changes will be highly variable, depending on the type and structure of the company, the technology to be regulated (or re-classified), along with the availability of regulatory support, including in-house or through an external supplier.
Period needed to implement the proposed changes.	• The period needed to implement these changes will be dependent on the type and structure of the company, the type of regulated technology, along with the availability and capability of regulatory support.

	• Consideration as to the level of support required of the TGA in provision of pre-submission consultations and the support of education and support resources during transition period is suggested as this level of support will impact the time organisations need to implement the proposed changes.

APPENDIX 1: REGULATION SECTION OF DIGITAL HEALTH INDUSTRY REPORT

DIGITAL HEALTH: CREATING A NEW GROWTH INDUSTRY FOR AUSTRALIA

Strengths, Opportunities, Constraints and Barriers to the Commercialisation of Evidence Based Digital Health Technologies in Australia

ANDHealth
Australia's National Digital Health Initiative

[REGULATION]

"The decades old regulatory paradigm just did not contemplate the challenges that we see with the rapid innovation and iterative nature of software, so the precertification pilot for us was the first step in trying to find a more fit-for-purpose regulatory paradigm,"

Danelle Miller, Vice President of Global Regulatory Policy at Roche[25]

KEY MESSAGES

- Companies seeking to scale internationally must consider medical regulatory frameworks, quality management requirements (ISO), data security and privacy requirements (HIPAA, GDPR, SOC, etc.) and reimbursement requirements.
- Approvals in some jurisdictions can ease the regulatory and compliance pathway in other jurisdictions, so the sequencing of approvals is an important factor.
- Clarity and consistency within regulation and expert guidance are required to support understanding of the regulatory framework to minimise risk for product development, commercialisation and investment.
- In order to fully realise the health and economic benefits inherent in evidence-based digital health, new models/ evolution of regulation and reimbursement frameworks need to be considered in Australia.
- New methods of regulation such as Secondary use of Data (Finland) and Pre-cert programs (US FDA) which have been developed in major jurisdictions, can be used to inform new/ evolving frameworks for Australia to accommodate new products such as digital therapeutics.
- Digital health innovators should be encouraged to view regulation as a competitive advantage, as it can smooth the adoption and customer acquisition process by indicating a product is safe and efficacious as verified by an independent body, the regulator.
- The regulatory framework around access to health data needs to enable innovation while protecting consumer interest and engendering consumer trust.
- Most therapeutic and medical device regulatory and reimbursement frameworks were developed prior to widespread adoption of connected technology solutions such as smartphones and the internet. Across many sectors, including healthcare, existing regulation often fails to keep pace with new technologies, leading to regulatory grey areas and limiting the rate at which the digital health sector can deliver transformative solutions.

BACKGROUND

The World Health Organization has recognised Australia's expertise in healthcare regulation and facilitates collaboration between Australia and other countries to support strengthening healthcare regulatory systems internationally[26]. In addition, we have a robust regulatory environment for the protection and use of health data. However, the pace of technological change and the rapid emergence of disruptive products and services are creating challenges for regulators on a global scale.

In healthcare, industry recognises that disruptive digital health products and services pose challenges for both regulators and government funded reimbursement programs, but also believes this disruption offers opportunities to transform approaches to regulation (especially in post-market monitoring) and, in some cases, offers a genuine case for reimbursement on a value-based basis.

In addition, clarity and certainty around the regulatory pathway and subsequent reimbursement opportunities are critical to swift and cost-effective commercialisation, which can place regulators and governments under significant pressure to adapt regulatory and reimbursement frameworks, whilst needing to preserve the necessary quality and evidence thresholds with respect to safety, efficacy and value, in both pre and post-market contexts.

It can be difficult for regulators to adapt to changing regimes around the world and to meet industry's expectations of regulation in areas that are constantly evolving. Over the years, the amount of existing legislation, regulation, and the associated administrative formality can become inefficient and burdensome[27].

For Cochlear, an Australian exporter of medical devices, a new product cleared by European regulators took a full 14 months longer to clear safety checks in Australia — during which time it wasn't available to patients in either market.

Barriers to Prosperity: Red Tape and the Regulatory State in Australia[28]

For digital health regulation there are a number of international activities that our regulators can look to for information, inspiration and guidance.

One model which is attracting increasing attention from the global digital health community is the US Food and Drug Administration's (FDA) current pilot of the Digital Health Software Pre-Certification (Pre-Cert) Program,

Traditional industries are being disrupted and the distinctions between industry sectors are becoming blurred as tech firms move into new areas like banking, retail and healthcare. Our traditional regulatory approaches, which take a sectoral approach, may no longer be appropriate.

Digital Economy Strategy team
Department of Industry, Innovation and Science

which encompasses products categorised as Software as a Medical Device (SaMD)[29]. The premise behind the program is that the FDA certifies the company that creates the product, and following this company-wide certification, new products released by the company are deemed "pre-certified" and as such benefit from an expedited approval pathway. Once approved, products then go on to meet usual post-market monitoring and reporting requirements.

For the pilot program, the FDA selected nine companies from more than 100 that expressed interest: Apple, FitBit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool and Verily.

The FDA believes the pilot can be used to inform the development of a new regulatory model that enables the least burdensome regulatory oversight with a tailored, pragmatic approach that does not inhibit access to technology for patients. In addition, the real-world data collection capabilities of SaMD products create a unique opportunity to add value to post-market monitoring and reporting. During the pilot the FDA is working with companies on the best way to collect and interpret real-world data on patient experience, software performance and clinical outcomes to monitor and improve performance, safety, effectiveness and address emerging risk.

Activities such as this, and current consultations being undertaken by the TGA with respect to SaMD regulation and Cybersecurity regulation in Australia, demonstrate the willingness of global regulators to adapt to disruptive technologies and to ensure that regulatory frameworks remain relevant.

[REGULATION]

STRENGTHS

Australia's Therapeutic Goods Administration (TGA) is a founding member of the International Medical Device Regulators Forum (IMDRF), a group of medical device regulators from around the world who meet regularly to accelerate international medical device regulatory harmonisation and convergence. The IMDRF management committee includes: Australia, Canada, Europe, Japan, Singapore, South Korea, and the United States of America, placing the TGA in an ideal position to maintain international leadership and be a driving force for harmonisation across major markets.

Key examples of this include:

- The TGA is currently undertaking extensive industry consultation and seeking to implement standards aligned with IMDRF documents for Software as a Medical Device (SaMD) - intended to identify commonalities, establish a common vocabulary and develop approaches for appropriate regulatory controls that promote prospective convergence in areas of advanced and innovative technologies[30].
- The TGA is also working with the IMDRF on Personalised Medical Devices to develop guidance that establishes definitions and regulatory pathways for Regulatory Authorities to consider in the regulation of medical devices that are intended for individual patients[31] such as 3D printed devices.

Australia has a strong legislative framework protecting the use of personal data, data privacy and data security requirements. Whilst data security, protection and use remains a topical issue in the public discourse, in general most parties agree that legislation with respect to personal data is well designed to protect consumers and researchers.

Roundtable participants observed that the TGA has made significant attempts in recent years to improve the regulatory process for SME's, specifically with respect to providing improved pre-submission interactions, and has taken steps to make itself more accessible for industry participants seeking advice and guidance on existing regulatory requirements, therapeutic goods classification and processes for regulatory acceptance. This consultative process supports the view of roundtable participants that the relatively small size of Australia supports greater access and consultation between industry and the regulators.

In general, roundtable participants felt that relevant regulatory clearances and approvals for digital health products and services were a positive aspect of creating an ecosystem that supported development, commercialisation and implementation of such products.

Attendees of the ANDHealth Roundtables agree that regulation should be seen as a competitive advantage for digital heath innovators, as it indicates a product can demonstrate clinical outcomes, which have been verified by an independent third party (the regulator).

Australia's position globally and our partnership with the international community are essential to ensure that products and services not only meet regulatory requirements within the Australian market but also have the ability to align to international standards and to enable export potential for key markets such as Europe (through the EMA) and the US (through the FDA).

OPPORTUNITIES

Roundtable participants agreed that there is a significant opportunity to leverage Australia's strengths in innovation, technology and health and medical research within the robust regulatory standards established by the TGA, to develop and commercialise evidence-based digital health technologies which can compete globally, forming the foundation of a new innovation-based growth industry.

Participants were all broadly aware of the FDA SaMD Pre-Certification Pilot program and were supportive of a similar approach being deployed in Australia, and encouraged the TGA to develop a regulatory information kit and education program to support industry awareness and utilisation of new regulatory pathways. Similarly, the consultation pieces being undertaken by the TGA in relation to SaMD and Cybersecurity are viewed as positive steps to clarify the regulatory environment.

The 21st Century Cures Act enables the FDA to use real-world evidence to approve medical devices and drugs using post-market data from health insurance registries, disease registries and other sources that can be used by the FDA to approve new uses of existing drugs. This has received a varied response as some see this as an attempt to replace the need for standard clinical trials, whereas others view it as utilising technology to improve the efficiency of regulation[32]. Australia has the ability to consider the impact of the 21st Century Cures Act as relates to the use of real-world evidence, and select key aspects of this regime that can drive regulatory efficiency.

Combining elements of the pre-certification concept with the use of real-world data and evidence (often patient generated) is the idea of an adaptive open outcomes based regulation (OOBR) regime – an adaptation of industry-led regulation for safety and efficacy based on the model established by the automotive industry. OOBR is a potential alternative review process for qualified medical products in which real-world evidence is used for the determination of long term risks and effectiveness. It leverages the tools of connected health to engage patients and collect data that is unavailable in standard pre-market clinical trials.

OOBR is intended to improve the review of innovative healthcare technologies, reduce the time and cost of pre-market trials and enable the continuous improvement of existing products[33]. Within the context of a review of regulatory systems to address the rapid, iterative development required for software based products (or devices with a significant software component), OOBR offers some ideas which regulators can consider as they look for new ways to regulate disruptive products and services throughout the healthcare system.

Beyond products and into data issues, the European Union's (EU) General Data Protection Regulation (GDPR) became enforceable beginning 25 May 2018, creating a requirement for Australian businesses "to comply with the GDPR if they have an establishment in the European Union (EU), if they offer goods and services in the EU, or if they monitor the behaviours of individuals in the EU."[34] These changes to data privacy and identity management provide an opportunity to assess the impacts (positive and negative) that this new regulation creates, and utilise these learnings to create a similar, aligned framework for Australia.

The Finnish Government's Ministry of Social Affairs and Health proposed a new act on the secondary use of health and social data. Their aim is to ensure flexible and secure use of data by establishing a centralised electronic licence service and a licensing authority for the secondary use of health and social data thereby increasing research and innovation activities relating to public health and wellbeing, disease prevention, and the development of new treatment methods.[35] Again, this provides an example that can be reviewed in the context of informing Australian regulatory frameworks.

For non-SaMD products a common consumer facing initiative is the digital services library that lists evaluated apps, portals, online services and wearables. Note that they are often called app libraries, as apps are the ubiquitous digital service for consumers.

New Zealand, Canada, the UK, and the USA have curated libraries. All libraries have similar objectives and processes for targeting digital services based on health priorities such as mental health and wellbeing. The UK has three libraries: one government and two private libraries that offer services to consumers and developers.

In Australia, there is no national standalone equivalent although there is evidence of curated libraries being utilised:

- VicHealth provides a service as a sub-section of its main Health website called the Healthy Living Apps Guide[36]
- Healthdirect Australia also includes some information about apps related to health topics on its consumer website[37]
- Primary Health Tasmania is currently using a privately developed Digital Health Guide[38]

There is a clear opportunity to develop a national consensus on a regulatory approach to evaluating SaMD, SiMD and non-clinical health apps to ensure informed choice for consumers and patients.

Currently Australian healthcare consumers have no easy way of assessing the applications they use, identifying which have clinical evidence supporting their claims and which are not evidence-based. Such a directory or ratings system would incentivise developers of both medical grade and direct to consumer health products and services to develop a evidence base.

[REGULATION]

BARRIERS & CONSTRAINTS

A recent CSIRO report found that Governments need to respond to an increasingly complex operating environment and start the process of defragmenting the sector-based approach to regulatory compliance and remove barriers to regulatory process efficiency.[39]

When considering the constraints and barriers in adapting regulatory frameworks it is important to consider that the healthcare sector is being impacted by a 'perfect storm' of significant macro-economic trends:

- healthcare expenditure takes up a significant and increasing proportion of GDP in most developed nations,
- the global population is aging,
- the required skill set for health care workers is changing; and
- delivery of care and development of new treatment modalities are being changed by the introduction of new technology.

A number of important sector-based structural foundations for regulations that have been built over decades to support the traditional healthcare sector are lacking the critical components required to support emerging digital health technologies.

Roundtable participants felt that there was existing uncertainty over the current regulatory regime that can increase perceived risk in these companies on the part of investors. Feedback suggested that it is often unclear whether or not a product should be undertaking a process of regulatory approval, and if it is decided to seek regulatory approval it is also unclear which process should be utilised.

"When viewed from the perspective of 'connected care', the Australian healthcare sector is severely fragmented, something that stems from a series of historical decisions that have left the market with numerous disconnects and 'rail gauge' problems.

[This has led to] numerous policy, administrative and compliance bodies and agencies operating at state, territory and Commonwealth government levels."

Flying Blind: Australian Consumers and Digital Health

Roundtable attendees noted that the TGA is a respected organisation that is generally accessible, open and collaborative, however identified that there are significant resource constraints in the funding model under which it operates. As a cost recovery agency, the Therapeutic Goods Administration (TGA) implements cost recovery activities associated with the registration and listing of medicines and inclusion of medical devices, including in vitro diagnostic (IVD) devices, and biologicals onto the Australian Register of Therapeutic Goods (ARTG) and the ongoing monitoring and surveillance of them.

While some funding is provided to the TGA by the government in the form of an interest equivalency payment against the special account balance (reserves), the vast majority of funding is generated through fees and charges charged under cost recovery arrangements. This leaves limited budget available for activities such as developing educational materials and undertaking industry information and consultation sessions.

The centralisation of regulators has worked while they have been able to maintain expertise and cope with the volume of work for evaluation, oversight and continuous quality review. However, the volume of digital health technology is challenging the capacity and capability of government and regulators to review existing legislation, regulation, and meet operational requirements that are needed to provide timely approval and ensure patient access and positive health outcomes.[40]

While industry and government continue to invest heavily in digital health technology there is a vital lack of experience, knowledge bases and data that can inform:

- organisational readiness,
- the efficacy of digital health interventions,
- outcome measurement,
- best-practice approaches,
- the expertise required for training, integration with existing workflows; and
- access and use of data to improve safety and quality.

Finally, data is the cornerstone on which the success of a digital health ecosystem is built, however currently multiple government departments and agencies regulate what data is collected and how it is codified, stored and shared. This segmented and fragmented approach to regulation creates barriers to the safe and efficient sharing of personal health data.

"Health data is regulated by the Australian Government Department of Health (and its many agencies), state health departments, private and public health insurers and accident compensation insurance schemes. Each stipulates the mandatory minimum data set requirements that health service providers are required to collect and report to them. The reporting mechanisms and details (56) vary between public and private medical and hospital service providers. This diversity combines to weaken the basis upon which funders, policies agencies and compliance agencies make significant decisions related to policy, planning, safety and quality, which in turn directly and indirectly compromises consumers' health."

Flying Blind: Australian Consumers and Digital Health

[REGULATION]

RECOMMENDATIONS

Regulation provides a critical framework that influences whether evidence-based technologies thrive or die. The overarching view of roundtable participants was that all healthcare focused technologies should have to substantiate their health claims via robust clinical evidence, verified by an independent regulator.

In support of this, the TGA should be financially supported to provide greater industry engagement activities, specifically in relation to improving information materials and undertaking industry consultation and education sessions.

Navigating the labyrinth of regulations is a costly challenge for many digital health companies. Industry, government and regulatory professionals should come together to support our future innovators to accelerate the growth of this new sector.

Paul L. Clarke, Paul L Clarke and Associates ANZ MedDev Specialists

Roundtable attendees recommended extending a number of recommendations encompassed in the CSIRO Medical Technologies and Pharmaceuticals roadmap specifically to digital health technologies: [41]

- A nimble regulatory framework that addresses industry concerns and which is clearly and effectively communicated (which may utilise elements of the OOBR regime).
- Regulatory agility including addressing uncertainties regarding reimbursement (extending beyond bionics and bespoke implants to digital therapeutics and other digitally enabled healthcare interventions).
- Regulatory Sandbox – Creation of a Regulatory Sandbox to facilitate development and commercialisation of evidence-based digital health solutions.

Engagement between industry and the TGA could be enhanced with respect to developing a suitable framework for the broad spectrum of digital health technologies via:

- More effective communication between the TGA and industry, especially with respect to works being undertaken in the fields of SaMD and cybersecurity.
- Once new classifications and regulatory frameworks are in place, undertaking extensive industry workshops to inform industry and service providers operating in the space as to the processes, timelines, expectations and costs of regulatory approval with respect to digital health products.
- Creation of a TGA-led, industry advisory committee to bolster the regulator's skills / capacity to take a more proactive role in developing and/or amending regulatory frameworks to support growth in the digital health sector.
- Improved educational and information materials, especially with respect to SaMD and digital health products, incorporating clear outlines of necessary regulatory requirements, processes and approval pathways and associated timelines and costs.

Look to overseas regimes where the digital health sectors are more mature and seek to align regulatory frameworks to reduce costs (including ongoing compliance costs) and increase certainty in commercialisation of new products, such as:

- Monitoring the outcomes of the FDA Pre-Certification Pilot and seek to undertake a similar study here in Australia to illustrate streamlined regulatory pathways for SaMD companies following reclassification activities currently underway.
- Streamlining the regulation of data use, storage and security across the many different departments and agencies across Australia as outlined in the Flying Blind: Australian consumers and digital health report. [42]
- Assess the impacts of the GDPR regime as it is adopted in practice across Europe and consider aligning Australian data privacy and security regulations with it.
- Consider the creation of a curated library of health applications which are supported by clinical evidence, potentially extending this to a "heart tick of approval" style system for consumer facing applications to better inform consumers of the validity of the applications they are purchasing and using in their daily lives.