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ANDHealth
Australia's National Digital Health Initiative

CONSULTATION: SCOPE OF REGULATED SOFTWARE-BASED PRODUCTS

Feedback to the TGA's Consultation Document | May 2020

ANDHealth Limited wishes to acknowledge the contribution of its Members in preparing this submission

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Feedback to the TGA's Consultation

Consultation: Scope of regulated software-based products.

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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.

Feedback received from the previous consultation on Regulation of software, including Software as a Medical Device (SaMD) that closed on 31 March 2019, indicated that there was confusion over what was considered a medical device. Consequently, it was considered important to clarify this in consultation with stakeholders prior to the commencement of the regulatory changes.

The TGA has proposed a series of exemptions to classification as SaMD, based on the consultation feedback received. This document is a response to the exemptions and clarifications proposed in Consultation: Scope of regulated software-based products.

In considering what could potentially be carved out from regulation the TGA have proposed exemptions following the principles that they:

- Align internationally where appropriate.
- Work to reduce or remove unnecessary regulatory burden:
  - by not regulating products where there is no a risk to safety (a no-harm principle)
  - by not regulating twice (that is, where suitable frameworks for product or system oversight are already in place)

OVERVIEW OF ANDHEALTH'S POSITION ON DIGITAL HEALTH REGULATION

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.

ANDHealth, as an organisation, advocates for appropriate regulatory oversight of digital health technologies. This is 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.

POTENTIAL SOFTWARE EXCLUSION/EXEMPTION, WHERE IT MAY BE CONSIDERED THAT THE SOFTWARE POSES NO POTENTIAL FOR SIGNIFICANT HARM TO A PATIENT

The proposed exemption states that:

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.*

ANDHealth's comments:

We agree with the principles expressed here and the proposed exemption however note that the definition of mild or self-limiting is important to the safety of this exemption going forward. The inclusion of "mild and self-limiting" is an important inclusion. We note that as drafted this limit appears to only apply to software used by consumers that monitors a condition but not to software that helps patients self-manage a specific disease/ condition or that helps patients manage stress for mental health. It is not clear why the limitation should not apply to all software used by consumers.

ANDHhealth sees two interconnected difficulties with the framing of the limitation as "mild and self-limiting".

It is our experience that entities who want to bring consumer software to market will try to avoid regulation. This is particularly the case where it is difficult or time consuming to provide the verifiable, robust evidence to support any therapeutic claims. As a result, we consider that it is likely that this exemption will be widely used to market products that are unable to support the therapeutic claims—perhaps creating a market for "digital snake oil". This will be made worse where the scope of what is a "mild and self-limiting" is not clear.

Neither the term "mild and self-limiting" nor its constituent parts are used elsewhere within Australia's therapeutic goods regulatory regime. This means that the key limitation on exemption will be introduced without any support or precedent for what is actually meant. Does mean everything that is not "serious"—a term that is widely used and defined within the regulations? Or is it something that only includes some other category but not everything that is not serious?

The definition of serious is as follows:

> **serious**, in relation to a form of a disease, condition, ailment or defect, means a form of the disease, condition, ailment or defect that is:
>
> (a) generally accepted as not being appropriate to be diagnosed or treated without consulting a suitably qualified health care professional; or
>
> (b) generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified health care professional.

ANDHealth submits that substituting "not serious" for "mild and self-limiting" is likely to provide a clearer exemption and one which better respects the purpose of regulatory oversight of consumer software that is a medical device.

ANDHealth also submits that the "not serious" limitation on the exemption should apply to each of the proposed types of software and not be limited to "monitoring" software.

POTENTIAL SOFTWARE EXCLUSION/EXEMPTION, WHERE ADEQUATE ALTERNATIVE MECHANISMS OF OVERSIGHT EXIST

The proposed exemption states that:

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.

...

It is proposed that Clinical Decision Support software may 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.*

ANDHealth's comments:

We appreciate that it is important that software that is already the subject of appropriate oversight is not unnecessarily subject to additional oversight.

However, in relation to wide principle and the proposed exemptions as currently framed, it appears that it will be left to the supplier to determine when this applies and when the additional oversight is appropriate. Where these exemptions are granted—such as for laboratory software—the alternative oversight should be specified by reference to particular standards and accreditation schemes.

Turning to the proposed exemption for Clinical Decision Support software, ANDHealth has concerns with two aspects identified above.

Where the software, is "providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition" ANDHealth considers that it is unreasonable to assume that a busy healthcare professional will review and verify software recommendations. Consequently, ANDHealth does not consider that such software should fall outside regulatory scrutiny.

If the intention of the requirement that the purpose must enable "such health care professional to independently review the basis for such recommendations" is to limit the exemption to exempt software that is unearthing further information and data, with, for example, links to evidence and studies, offering a full suite of alternatives to support the clinician's decision, then an exemption is supported.

While presenting a clinician with timely evidence-based information should not require regulatory oversite, de-facto diagnosis or suggestion of treatment methods, with the expectation on the health care professional to independently review the recommendations, may prove unreasonable in practice. ANDHealth considers the risk is that the software could become a de-facto decision maker for the clinician. The realistic likelihood of a health care professional being able to independently review the basis for the decision made by software is brought into question. It is very difficult for a health care professional to independently review the basis for a recommendation if the recommendation is provided by a machine learning or AI algorithm.

Consequently, ANDHealth considers there is a real risk that this will provide exemptions to algorithmic assessment of patients and providing health care professional with recommendations for prevention, diagnosis, or treatment of a patient without any realistic prospect of the health care professional to look behind the recommendations. ANDHealth considers that such software should be subject to the scrutiny of the safety, quality and efficacy of the basis for the recommendations made to the health care practitioner that would occur where it was subject to the requirements for medical devices

If this true meaning of what enabling independent review in this exemption remains open to interpretation, it is likely to be used to argue that simply because a health care professional must exercise professional judgment in implementing any recommendation, it will be satisfied. It must be clear that the exemption does not extend to software where a health

care professional might rely primarily on any recommendation to make a clinical diagnosis or treatment decision regarding an individual patient.

Broadly ANDHealth members feel that if the product is driving a clinical intervention or claiming a clinical impact, clear evidence must be provided to regulators to substantiate the product claims, as required through regulation. We believe that genuine companies shouldn't find this an issue, however the exemption may open a pathway for products that are less evidence-based to seek a loophole and avoid providing evidence for their claims.

ANDHealth submits that exemptions for software as a result of adequate alternative mechanisms of oversight should not leave the determination of which alternative mechanisms of oversight are adequate at large and should instead specify particular standards or accreditation schemes (or combinations standard and accreditations) that are considered adequate.

ANDHealth submits that Clinical Decision Support software should only be exempt where it works to provide healthcare practitioners with timely evidence-based information to support or decision making about prevention, diagnosis, or treatment of a disease or condition but that where a recommendation is provided by a machine learning or AI algorithm, that underlying system should be subject to scrutiny in relation to the safety, quality and efficacy of the basis for the recommendations.