Australian Government
Department of Health
Therapeutic Goods Administration

Analysis of submissions from the consultation: Scope of regulated software based products

Version 1.0, August 2020

TGA Health Safety Regulation

Contents

Analysis summary

The TGA released a public consultation paper in April 2020 seeking feedback on proposals to "carve-out" from regulatory oversight by the TGA, certain groups of software medical device products that would normally be regulated by the TGA under the Australian medical devices regulatory framework.

There were 48 submissions and in June 2020, TGA published the submissions and a brief summary of them on the TGA website. This document provides an analysis of the submissions provided by respondents. A more concise four page summary document is also available on our website.

Overall, there was broad support to carve out products that pose no potential for significant harm to an individual that can be grouped in the following way:

i. Patient/consumer health life-cycle - prevention, management and follow up

ii. Enabling technology for telehealth, remote diagnosis, health care facility management

iii. Digitisation of paper based or other published clinical rules or data

iv. Population based analytics

Two further categories can be grouped for carving out. There were mixed views about the carving out of Clinical Decision Support Systems, indicating that further work is needed on definitions and criteria. There was support to carve out systems that had alternate regulatory oversight such as Laboratory Systems.

Some submissions raised additional issues including definitions of health software and SaMD, oversight of consumer apps, mobile apps, artificial intelligence, data and general purpose hardware.

Based on the feedback, the TGA will hold discussions with targeted respondents on their comments, or to seek further information prior to advice being provided to the Government.

Summary of the consultation paper

In 2019, the TGA conducted consultations and workshops with external stakeholders about regulation of software as a medical device to develop advice for Ministerial consideration on the scope of the regulatory scheme. There were further discussions with stakeholders on clarifying boundaries for software based medical devices that are, in law, regulated under the *Therapeutic Goods Act 1989*, but could potentially be exempt or excluded (i.e. "carved out") to ensure that industry sponsors and manufacturers are not subject to unnecessary regulatory burden.

In February 2020, TGA released a public consultation paper seeking feedback on whether there were instances where the medical device presents a lower risk to safety or where a device may already be subject to alternative oversight under another regulatory framework that could therefore inform a potential carve-out. The consultation paper presented a number of international examples of carve outs in place in the USA, Europe and Canada, along with other examples identified through discussions with stakeholders, including the National mHealth apps Reference Group, established in February 2019.

In considering what could potentially be carved-out from regulation, the following principles were proposed:

- Align internationally where appropriate.
- Work to reduce or remove unnecessary regulatory burden:

- by not regulating products where there is no a risk to safety
- by not regulating where suitable frameworks for product or system oversight are already in place.

There were 48 submissions and in June 2020, TGA published the submissions and a brief summary of them on the TGA website. This document discusses the responses to the 2020 consultation paper.

Exclusion vs Exemption

Under the *Therapeutic Goods Act 1989*, there are two means for legally carving out certain software-based products either in full from being regulated as medical device or from selected requirements—*exclusions* and *exemptions*, where:

- An **exclusion** means that the specified products are **not subject to regulation** by the TGA. Specified products may be excluded for all applications (excluded goods) or, alternatively, only when used, advertised, or supplied in a specified manner for a particular purpose (excluded purposes).
- **Exempted** products **do not have to be included in the Australian Register of Therapeutic Goods** (and thus an application relating to the product does not have to be submitted to TGA for review) but they are still subject to some aspects of regulatory oversight by TGA. An exemption can either be made for a product without conditions or else may be made subject to conditions that can be prescribed in the Regulations (e.g., exemption for a specified product when supplied to a certain type of facility or for a specified purpose).

Table 1: Summary of requirements for Excluded versus Exempted products

Requirement	Exclusion	Exemption
Requirement to be included in the ARTG	No; Excluded products are not able to be included in the ARTG	No; It is possible for exempted products to be included on the ARTG if the sponsor so chooses
Sponsors of exempted devices must ensure that the products meet the relevant essential principles for safety and performance	No	Yes
TGA monitors on going safety of products after they are made available	No	Yes
Manufacturers/sponsors must report adverse events to the TGA	No	Yes
TGA can take regulatory actions such as recalls or issuing hazard alerts in the event of a problem	No	Yes

Requirement	Exclusion	Exemption
Products are subject to the Therapeutic Goods Advertising Code	No	Yes (unless otherwise exempt)
Products are subject to relevant consumer laws	Yes	Yes (?)

The consultation paper provided a number of examples of both:

- Software that **is a medical device** under the current application of the Therapeutic Goods Act (but may nonetheless be potentially carved out by an exemption or exclusion):
  - Diagnosis of an individual's disease or condition
  - Monitors an individual's disease or condition
  - Provides therapy to an individual.
  - Controls other medical devices
  - Is an accessory to a medical device
  - Recommend or specify a treatment or intervention specific to an individual
  - Software used to generate virtual anatomical or physiological models.
- Software that **is not a medical device** under the current application of the Therapeutic Goods Act (a table was provided at Appendix 3 of the paper). The paper also highlighted a number of specific examples of software that may currently be captured as a medical device that could be considered for exclusion or exemption.

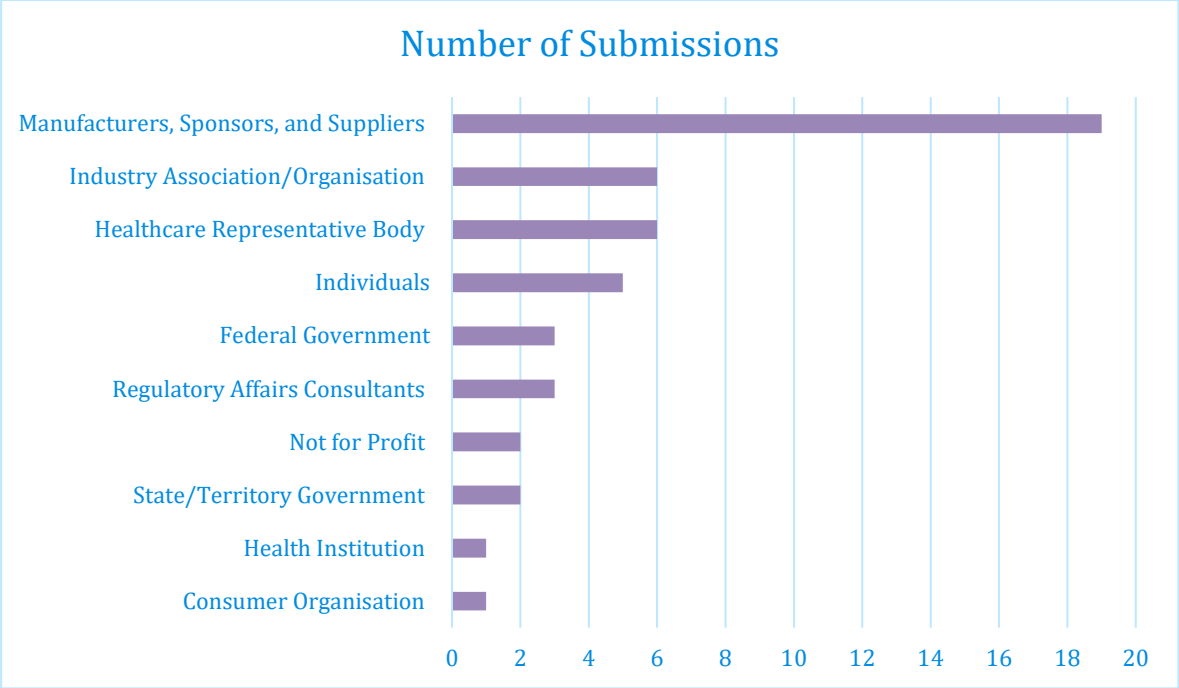
  Software that could be potentially excluded or exempted from regulation where it is considered that **the software product does not pose significant harm** to the individual (e.g., due to inappropriate use of the product):
  - Software used by consumers (Patient information and health management):
    - § 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[1].
  - Software used by health professionals:
    - § Software that provides "class-based analyses" rather than patient-specific diagnosis or management

[1] 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 description of which conditions could be excluded or exempted from the software regulatory regime.

- Potential software exclusion/exemption, where **adequate alternative mechanisms of oversight exist**:
  - Lab Support Software that is intended to be used in an accredited pathology laboratory and 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.
  - Clinical Decision Support Software 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 the 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.

Summary of responses

48 submissions were received, categorised by the type of respondent below:



The submissions showed broad support for the principles put forward in the consultation paper, such as international alignment, and for the potential to carve out products where there is existing regulatory oversight that would be duplicative, and/or particular types of software pose no potential for significant harm to an individual. However, other than for laboratory activities, few submissions described in any detail existing systems potential mechanisms for alternative oversight.

There were a small number of other software products identified by respondents for potential carve-outs. Several examples suggested for exclusion or exemption were already out of scope of TGA regulation as they do not meet the definition of a medical device.

It was apparent that the distinction between an 'exemption' and an 'exclusion', and the implications for the treatment of particular groups of products needs to be more clearly explained by the TGA.

Several respondent suggestions were either examples provided in the consultation paper of software **that is (already) not a medical device** so would not require carve-out. These included software involved in:

- Administrative support of a health care facility
- Management of prescription information
- Medication/adherence (treatment regimens)
- Electronic Patient Records
- Clinical Workflow and Support
- Used for education, training, or guidance
- Extracting, transferring, storing, converting formats, or displaying clinical laboratory tests or other device data and results

- Processing or communication tools; Health information management/database systems
- Maintaining or encouraging a healthy lifestyle
- Monitoring or management of Health IT systems, or IT equipment where the manufacturer is not making any therapeutic claims
- Medi-alerts, and
- Travel Medicine Tools

There were a range of views around potentially excluded or exempted software from regulation, in the category proposed in the discussion paper as "software that poses no significant harm to a patient", including:

- Helps patients self-manage a specific disease/condition
- Helps patients manage stress for mental health
- Monitors a condition
- Software used by health professionals

Most submissions supported carve out but several submissions opposed exclusion or exemption from regulation.

Some submissions proposed additional examples of software for exemption/exclusion:

- Patient outcome registries
- Simple calculations (e.g. for dosage, blood gas calculation)
- Medication reminders
- Decision support software used in the manufacture of therapeutic goods

Patient outcome registries and medication reminders would not generally meet the definition of a medical device. Simple calculators may or may not be depending on the exact nature of the calculation, and this will need to be clarified in the regulation. Software used in the manufacture of therapeutic goods may be considered a medical device.

A submission from the disability products sector highlighted that Assistive Technology (AT) software should be excluded, including

- hardware devices that may host AT software
- software/apps for those with communication disability
- AT location devices – e.g. used to track location of a dementia patient
- AT computer aids – e.g. voice controls to manage computer functions

These were not envisaged for regulation as medical devices in the consultation but it will be important to clarify in regulation that a range of assistive technologies are excluded.

Several submissions proposed patient survey and self-assessment questionnaires (e.g. those reporting patient reported outcome measures) for exemption. In some cases this extended to software that performed an analysis on this information to produce a risk score for a particular condition.

One submission (from Cochlear) suggested it may "be appropriate to exempt all medical device software that is purchased directly by the patient/consumer for their own individual (or 'personal') use. For example, any smartphone app (that is also a medical device) that is downloaded by an individual consumer for their own personal use."

The example provided by Cochlear was for "software which is used by an individual to check or test their own hearing performance (for example, with or without with hearing aids), so that they are aware when their hearing drops below a certain threshold, and they can decide to visit their hearing healthcare professional for a more thorough assessment"

The response did not suggest that such exemptions be based on the risk of the software. Several other submissions expressed a contrary view - that software that was targeted in a direct to consumer manner may be higher risk and should not be carved-out from TGA regulation.

Some respondents identified additional types of software for consideration for carve out. Some of these are considered as subsets of the software already proposed for carve out in the consultation paper, but it highlighted the need to provide further clarification in proposed regulations:

- **Apps that connect to MyHealth Record** – Whether these apps would be regulated by TGA or not depends on what these apps do with the information they extract from the electronic health record.
- **Systems that record and store patient images** – Systems that store medical device data, such as patient images, were provided in the consultation paper as an example of a product not meeting the definition of medical device. However, systems that record patient images directly (e.g. x-rays) would generally be considered medical devices.
- **Software that is used by health professionals "who can exercise their own judgement"** and "**information systems used by GP practices and individual GPs"** – These are considered to require treatment in a similar manner to clinical decision support software.
- **Software embedded in the delivery of health services** – Whether this software is in or out of scope depends on its function.
- **Middleware that does not recommend a diagnosis or treatment decision** – These would not meet the definition of medical device, e.g. processing tools (for transferring, storing, converting formats, archiving, encrypting data) and communications tools.

Other products highlighted were:

- **Patient surveys that form part of an electronic health record and patient recorded outcome measures** (with no risk scoring or analysis) are proposed for carve-out. This would also be when they are part of an EMR/EHR or stand-alone.
- **IVD software** (for commercial and in-house IVDs) and software for **genomic interpretation tools** will be considered separately in further consultations on the regulation of IVD software.
- **3D printers that create anatomical or physiological models** and **custom made devices** that may have software components. These would fall under the personalised medical devices regulatory framework which has been the subject of recent reform).

Response to Question 1: Exemption

Several submissions suggested that any software not subject to medical device regulations in specific international jurisdictions should be treated similarly in Australia. In particular, guidance outlining such software from the US FDA, Health Canada and the UK MHRA were referenced. In general, it is intended that that the carve outs in Australia be similar (and in some cases greater than these jurisdictions). However, certain manufacturers in the US receive less individual product oversight because they are participants in the pilot "Pre-cert" system which provides a range of manufacturer-specific assurances. At this stage it is not possible to obtain these US company evaluations (nor is it currently cost-effective to establish a similar Australian pre-cert scheme) so in these cases the Australian oversight is necessarily product-based.

Response to Question 2: Exclusion

Submissions generally supported the carve-out of certain software being made according to risk based exclusion criteria. Several responses addressed the two specified carve-out principles put forward as questions in the paper.

No potential for significant harm to an individual

There was general support but it was emphasised that the definitions required further clarity, such as the definitions for "significant harm" and "mild and self-limiting".

Some submissions stated that devices that "are considered to pose no significant threat of harm" is too high a level of risk for a medical device to be allowed to be unregulated or have a reduced regulatory oversight. For example, the AHHA noted that "Without seeking to place unnecessary burden on producers of software-based medical devices, the higher public policy priority is patient and public health safety, and the relevant threshold should reflect this." The AMA noted that "If a software satisfies the legal definition of a medical device, it is unlikely, to impose nil risk of potential patient harm."

AbbVie suggested that appropriate disclaimers could reduce the harm posed to an individual, "e.g. recommendations are for guidance only, and should not be used solely for the purpose of making a clinical decision or diagnosis. Evidence to support this could be considered as a product characteristic in determining the level of risk."

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

Several submissions proposed that the definitions used in US FDA and Health Canada guidance documents could be used in determining the types of software that pose no potential for significant harm to an individual.

Schemes for alternative regulatory oversight

The submissions supported carve-outs where there were established alternative oversight schemes in place. Most submissions did not discuss specific additional alternative oversight mechanisms, but provided feedback on the two examples provided in the paper (clinical decision support and lab support software).

Some submissions suggested that when additional oversight came from the health care professional or clinician intended to use the software, there could be additional carve outs. However this principle was not supported in some other submissions. For example, the MSIA

"recommends that the two carve out principles … be extended to include a third. This would be the principle of appropriate oversight by qualified health professionals"

In contrast, the AMA commented that "…the regulation of registered medical practitioners under the Medical Board is not a sound justification for automatic exemption of software-based medical devices used by medical practitioners. This proposition would pass responsibility for device safety and quality, efficacy and performance from the software developer/manufacturer, to the medical practitioner user.

"It is totally unacceptable to expect the medical practitioner, device user, to bear responsibility for patient harm under their own medical board regulation, when the patient harm is a direct result of erroneous information produced by a poorly designed software medical device."

Various submissions suggested a range of organisations could be involved in oversight, including the ACSQHC, the ADHA, professional Colleges (e.g. RACGP and RCPA), and associations (e.g. Pharmaceutical Society of Australia). However most of these do not have a regulatory role or any compliance powers.

Clinical decision support Systems

There was broad support for clinical decision support software to be exempted or excluded but under specific conditions. There was broad agreement with the conditions put forward in the consultation paper because the clinician provides a layer of additional oversight for these systems:

- 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.

There was a suggestion that all four of the criteria may not need to be satisfied to qualify for a carve-out. However several submissions (e.g. AMA, RACS ASERNIPS, and ANDHealth) argued that reliance on a health provider to mitigate inadequately validated software products is unacceptable.

The AMA suggested a conditional exemption for clinical decision support software that fits the legal definition of a medical device "has the potential to become very confusing for medical practitioners. It is unclear how the TGA will monitor the continued appropriateness of a regulation exemption if, over time, the designer/developer changes the software algorithms and distributes these changes via software upgrades."

ANDHealth highlighted that they consider "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.

Laboratory support software

There was broad support for Laboratory Support Software to be either exempted or excluded from inclusion in the ARTG, where alternative oversight exists. This includes

- Laboratory Support software or Laboratory Information Management Systems (LIMS, used in an accredited pathology laboratory, or
- Facilities that have either/both NATA pathology accreditation or a TGA GMP licence.

Pathology Technology Australia suggested that "Laboratory Information Management Systems and Middleware software, that do not recommend a diagnosis or treatment decision and that do not message IVD instruments should be exempt."

Response to Question 3: International jurisdictions

International alignment was supported in most submissions, although different respondents provided specific mention of the EU, US, UK and Canadian regulatory schemes for SAMD as well as IMDRF guidelines. What was clear is that there is not full alignment between the different overseas regulatory schemes.

The proposed carve outs in the consultation paper do align closely with similar carve-outs undertaken by international regulators, although slightly more extensive. The UK MHRA definitions of "medical purpose" for software and "non-medical" functions have informed our definitions.

The EU regulations are less specific and may not carve out software that acts on data to the same extent as is proposed in Australia. The US FDA maintain a range of software within their medical device framework but propose to use "enforcement discretion" for certain software functions. It is proposed that these functions e.g. which self-manage conditions or automate simple healthcare provider tasks are instead carved out in Australia to provide greater clarity. The proposed Australian scheme aligns most closely with the Canadian scheme, although more carve-outs for clinical decision software are envisaged in Australia.

There is no additional regulatory burden where certain carve-outs are slightly greater in Australia than in comparable countries; submissions made to (and evaluations by) comparable overseas regulators can be provided to the TGA to streamline our regulatory evaluations. Several submissions commended the Health Canada *Guidance Document: Software as a Medical Device (SaMD): Definition and Classification* which was seen as providing a readable description of inclusion and exclusion criteria for Software as a Medical Device.

In summary, feedback indicated that the TGA needed to develop a brief statement on international regulatory alignment and use of Comparable Overseas Regulator reports to assist understanding of how to reduce regulatory burden and make clear where differences occurred – i.e.: transparency to assist market entry

- Minimise unique Australian requirements (however some respondents did not recognise that the major jurisdictions are inconsistent in carve-outs)
- Enable regulatory submissions and evaluations from comparable regulators (where available) to be used
- Canadian guidance and approach seemed simplest and clearest
- Are there specific mechanisms used in international jurisdictions noting that
  - The EU regulations lack sufficient specificity on carve-outs
  - the US FDA "Pre- cert" approach while reducing regulatory burden on sponsors would be too resource intensive for TGA to implement at this stage)

Summary of other comments

Guidance, definitions and scope

Many submissions highlighted the need, as well as providing carve-outs in regulation, for TGA to publish guidance on the scope of regulated products.

It was asked that clarity be provided around the terms critical for defining the boundary of regulated products, such as: ***medical device, intended purpose, medical purpose (or therapeutic purpose and clinical purpose).*** For example, where monitoring devices may not be covered, when intended to monitor without a therapeutic purpose e.g. for general health and wellbeing. This included the terms used to define the carve-out principles: ***significant harm, public health, alternative regulatory framework.***

There were also requests for guidance on specific software technologies including AI, virtual technologies, natural language processing, Internet of Medical Things and IVD software.

Software as a Medical Device (SaMD) is a subset of health software

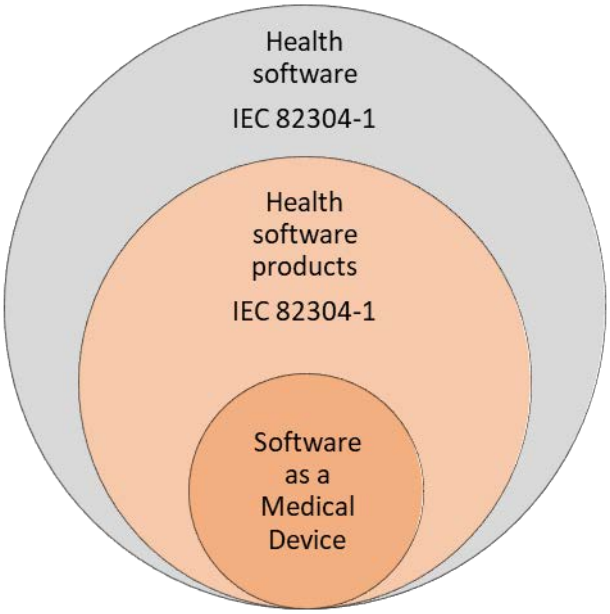
Feedback to the consultation indicated that this differentiation needs to be made clear in any future TGA guidance material.

Health software is defined in the standard ISO/IEC 82304-1 (2016) "Health Software - General Requirements for product safety" as:

"software intended to be used specifically for managing, maintaining or improving health of individual persons or the delivery of care"

The scope of 'health software' in IEC 82304 is broader than medical device software. Most health software is not a medical device and is not regulated by the TGA.

The diagram below illustrates where SaMD sits in the broader category of the scope of health software:



Questions were raised about the use of data in software systems, including concerns around data integrity, privacy, issues with data aggregation, and cybersecurity and data drift (especially in relation to AI model training data).

Mobile apps

Due to their ease of access and mass adoption by consumers, some submissions highlighted mobile apps in particular. These are often consumer facing and intended to be used without the involvement of a health professional, potentially increasing the need for assurance or regulatory oversight.

In early 2019, the Government commissioned work on the design of a national framework that can increase public and health care professionals trust in the use of Mobile Health Applications (Apps) in Australia and encourage the use of safe and effective mHealth Apps to improve health outcomes. The framework does not yet have policy authority or funding for its implementation, but its aim is to provide a framework for oversight of software products that fall outside the scope of TGA regulation as medical devices. The Health Services Principal Committee (HSPC) endorsed the establishment of a time-limited mHealth Apps Project Reference Group, which has been overseeing the development of project design.

The policy objectives for government involvement are to:

- protect the public from harm
- assist consumers in their selection of credible apps
- assist health care professionals to make informed choices when recommending digital applications to their patients
- provide vendors with guidance and certainty about what is required when developing mHealth Apps
- support integration of effective and safe mHealth Apps into clinical workflows

The current regulatory arrangements provide a level of protection from harm to the public, but it is likely that consumers and health care professionals will require additional information on aspects like efficacy and useability of mHealth Apps. It is proposed that to achieve the policy objectives outlined above, there is a need for a national process for the assessment of mHealth Apps, in addition to the regulatory role of the TGA, OAIC and ACCC. A curated library of mHealth Apps could also be established, based on this national process. This would build greater trust in mHealth Apps and provide clinicians and consumers with further information to enable informed decisions about whether the mHealth Apps are safe and have the potential to improve health outcomes.

Particular categories of mobile apps for consideration were for self-management of mild conditions, Mental Health Apps and Lifestyle apps. Suggestions ranged from exempting all medical device software that is purchased directly by the patient/consumer for their own personal use, to ensuring direct to consumer products are safe and fit for purpose.

Artificial Intelligence (AI)

Several organisations noted that the consultation paper did not address AI technologies, and how they may be treated under the regulatory framework. AI presents a number of regulatory challenges since it would be hard for users of software to independently review the basis for a recommendation if the recommendation is provided by a machine learning or AI algorithm. In view of the rapid evolution of SaMDs including AI, it is planned that Australian guidance be developed as a separate initiative to considerations of carve-out of SAMD.

General purpose hardware

A request was also made for clarity on the regulation of the hardware that is required to run regulated software, in particular for commercial off-the-shelf platforms such as mobile phones, watches, tablets and personal computers.

One submission highlighted that a discussion on the scope of regulated software should also consider the computing platform required to operate the software.

Appendix 1 – Table of submissions by group

Type	Number	Organisation
Manufacturers, Sponsors, and suppliers	18	AbbVie Pty Ltd, [redacted], Boehringer Ingelheim Pty Ltd, Cochlear Limited, CSL Behring (Australia) Pty Ltd, Fresenius Medical Care Australia Pty Ltd, GlaxoSmithKline Australia Pty Ltd, GPC Systems Ltd (Australia), Hill-Rom Pty Ltd, Hydrix Limited, [redacted], [redacted], [redacted], ResMed Pty Ltd, Roche Diagnostics Australia Pty Ltd, Siemens Healthcare Pty Ltd, Smith & Nephew Pty Ltd, Telstra Health
Regulatory Affairs Consultants	3	Brandwood CKC, [redacted], Platypus Technical Consultants
Healthcare Representative Body	6	Australian Healthcare and Hospitals Association, Australian Medical Association, Royal Australian College of General Practitioners (RACGP), Royal Australasian College of Surgeons (RACS |ASERNIP-S), The Royal Australian and New Zealand College of Ophthalmologists, The Royal College of Pathologists Australia (RCPA)
Industry Association/Organisation	6	Assistive Technology Suppliers Australia, Japan Industrial Radiology Systems Association (JIRA), Medical Software Industry Association (MSIA), Medical Technology Association of Australia (MTAA), Medicines Australia, Pathology Technology Australia
Individuals	6	[redacted], Firme, Hayes, Lehmann, MacKenzie, Ramesh
State/Territory Government	2	[redacted], [redacted]
Federal Government	3	Australian Commission on Safety and Quality in Health Care, [redacted], [redacted]
Consumer Organisation	1	Health Consumers Alliance of South Australia
Not for Profit	2	Australia's National Digital Health Initiative, [redacted]
Health Institution	1	Victorian Clinical Genetics Services

Appendix 2 – Information provided on scope in the consultation paper

Medical device

Diagnosis of an individual condition	Skin cancer screening, software that provides information
Monitors an individual disease or condition	Software intended to analyse a medical condition - e.g. heart arrhythmia detection, eyesight deterioration
Provides therapy to an individual	Individual treatment plan for radiation therapy for lung cancer
Controls other medical devices	Implanted spinal stimulator, app intended to calculate insulin levels, software intended to analyse cardiac arrhythmias and treat patient with electric shock
Is an accessory to a medical device	Accessory to glucose monitor that reads blood strips and displays and stores results
Recommend or specify a treatment or intervention specific to an individual	Recommending particular types of laser eye surgery to eye surgeons
Software used to generate virtual anatomical or physiological models	Software intended to generate a patients anatomical model by processing images provided by CT or MRI

Not a medical device

Administrative support of a health care facility	Processing and maintenance of financial records, claims or billing information, appointment 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	Real time prescription monitoring or electronic prescription exchanges, e.g. electronic medication chart, electronic prescribing and support to check, order and record administration of medicine and software intended to provide secure and safe transmission of prescription information between doctors and pharmacists

Medication/adherence (treatment regimens)	Software intended to provide information on drug interactions, software intended to help patients improve medication adherence
Serve as Electronic Patient Records	Transfer, store, convert formats, or display the equivalent of a paper medical chart - medical data image for the purpose of diagnosis, prevention, treatment etc. of a specific disease or condition
Electronic Patient Record Keeping	Organise health information (manual patient recording of blood glucose, asthma attacks, blood pressure etc.)
Clinical Workflow and Support	Software to support health professional, software that is intended to solely display or print medical information about a patient or other medical information
Used for education, training, or guidance	Online textbooks, clinical guidance materials (including decision trees) for health professionals, software intended to help patients self-manage diseases/conditions through the provision of educational information
Transferring, Storing, Converting formats, or displaying clinical laboratory test or other device data and results	Findings by a health professional with respect to such data and results, general information about such findings and general background information about 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.
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 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 to aggregate information from different systems.
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.

Extract Data	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 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	Up to date travel vaccination advice and individualised vaccination scheduling
Predictive Analysis	Software intended to provide up to date travel vaccination advice and individualised vaccination scheduling
Archetype Editor	Software intended to be used by clinicians to develop and edit archetypes for use in both point-of-care and research settings

Potentially excluded or exempted from regulation

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	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. 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.
Software used by health professionals	Software that provides 'class - based analyses' rather than patient-specific diagnosis or management

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

Lab Support Software	LIMS: Intended for input, storage and retrieval of clinical information or data; and reporting of clinical information does not meet the definition of a medical device.
Clinical Decision Support Software	Criteria for carve-out: • 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.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #