Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Scope of regulated software-based products

March 2020

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA has issued this consultation paper as part of the Government's reform program.

Background

The definition of medical device in the *Therapeutic Goods Act 1989* (the Act) (Appendix 1) states that a medical device is any instrument, apparatus, appliance, material or other article intended to be used for:

- diagnosis, prevention, monitoring, treatment, alleviation of a disease, injury or disability;
- compensation for an injury or disability;
- investigation of the anatomy or of a physiologic process; or
- control of conception.

The manufacturer assigns the **intended purpose** of the medical device. The intended purpose is reflected in the labelling, instructions for use or any advertising material (including website advertising) provided with or for the device. For regulatory purposes, the intended purpose will determine the **classification of the device** and minimum **conformity assessment** procedures that the manufacturer must comply with for inclusion in the Australian Register of Therapeutic Goods (ARTG).

Conformity assessment procedures are requirements placed on the manufacturer of a medical device. They include controls around manufacture (design and construction) of medical devices, keeping and maintaining records, and managing complaints and recalls. The minimum conformity assessment procedures that apply are determined by the classification of the device. The procedures are followed by the manufacturer in order to demonstrate conformity with safety and performance principles (the essential principles of safety and performance). This principles-based approach provides flexibility for manufacturers of medical devices for how to demonstrate compliance and supports different technologies and technological advances over time.

The degree of oversight by regulatory authorities varies according to the classification of the device and the manufacturer's intended purpose for the device. There is a four-tier classification system for medical devices: Class I (lowest classification), Class IIa, Class IIb and Class III (highest classification). The higher the classification of the device the higher the level of regulatory scrutiny. Manufacturers of all medical devices, including software-based medical devices, supplied in Australia must:

- meet the minimum conformity assessment certification requirements appropriate to the level of classification of devices being manufactured; and
- have evidence that demonstrates compliance of their medical devices with the relevant essential principles.

The majority of Class I medical devices are self-certified and applications for inclusion in the ARTG are processed automatically with no assessment undertaken by the TGA. Manufacturers of Class IIa, Class IIb or Class III medical devices must obtain conformity assessment certification from an independent body (e.g, from a European notified body) or from the TGA prior to an

application being made for inclusion in the ARTG. Manufacturers of Class III medical devices are also required to have the design of their devices examined by the conformity assessment body.

The form in which the software is supplied does not determine whether or not it is regulated by the TGA as a medical device. For example, software can be a medical device in the form of:

- a mobile app for a smart phone or tablet;
- a program for a computer that is supplied on a device like a USB stick;
- software installed and supplied on a computing platform (like a generic smartphone branded by the software manufacturer); or
- a program that is accessed or used through a website.

Thus, if a software-based product fits this definition then the medical device is potentially captured under the regulatory framework. Many types of software meet this definition; some examples include:

- smart phone apps that calculate insulin doses based on a patient's blood glucose levels
- X-ray image-processing software
- software that uses information about a patient to make a diagnosis or to screen for a disease,
- a software app that specifies or recommends a treatment or therapy,

Consultation on the regulation of software-based medical devices

In early 2019, the TGA conducted a public consultation on the *Regulation of software, including Software as a Medical Device (SaMD)*. Proposals for change included:

- new classification rules for medical device software-based products (not including *in vitro diagnostic* medical device software); and
- changes to the essential principles for safety and performance of software-based medical devices to improve the clarity of requirements.

Regulatory changes based on government decisions following this consultation were made on 12 December 2019 to incorporate the changes mentioned above. The majority of the new requirements will be effective from 25 August 2020 but will include a four-year transition period for eligible manufacturers and sponsors (until 1 November 2024). A summary of the changes can be found on the TGA website here. Further detailed guidance is to follow and to some extent will be informed by this consultation process.

Summary of the new classification rules for software–based medical devices

The classification rules for software-based medical devices will result in higher risk products being reclassified at a higher level. This is to ensure such products are subject to appropriate scrutiny and manufacturing standards. The classification rules for software-based medical devices now consider the harm that could be caused by the provision of incorrect information in carrying out the medical device functions of the software, and determines the level of regulatory oversight it will undergo.

The new rules cover software-based medical devices intended for:

- Diagnosing and screening for a disease or condition
- Monitoring the state or progression of a disease, condition, etc.

- Specifying or recommending a treatment
- Providing therapy (via provision of information)

Please note

The new classification rules *do not apply* to IVD medical devices.

The former regulatory framework considered harm that can directly be caused by a physical interaction with a medical device; however, it did not adequately address the risk of patient harm where information is the source of harm. Software that processes data to provide information to be used in treating a person, for example, a diagnosis of a disease, or the specification of a therapy to be delivered, can cause harm when the information is incorrect.

The International Medical Device Regulators Forum (IMDRF) has developed guidance for the regulation of software to address such concerns and the EU has recently moved to reform its regulation of software-based medical devices in harmony with the IMDRF guidance. The EU introduced rules for software classification in its Medical Device Regulation 2017/745 which comes in to force in May 2020.

The Australian classification rules for software-based medical devices are broadly aligned with the EU classification described however, based on consultation feedback, the Australian rules also take into consideration whether the software is intended to provide information to a relevant healthcare provider. In accordance with the IMDRF principles, the rules recognise this as a lower risk scenario and the classifications are correspondingly lower than those in the EU. This means that EU certification will still be able to support an application for market authorisation in Australia because a higher certification level is acceptable for a product with a lower risk classification.

There are some additional differences compared to the EU classification rules. The EU rules are silent on public health risk and devices that provide therapy through the provision of information so these default to Class I in the EU. Depending on the intended purpose of the software, these devices may be Class I or higher in Australia. The Australian classification rules are summarised in Table 1 with further detail provided in Appendix 2.

As part of the personalised medical device reforms, change were also made to an existing classification rule to cover medical devices intended for creating virtual anatomical models (see Appendix 2). This is also not currently addressed in the EU medical device classification rules and so these devices would default to Class I in the EU but may be a higher classification in Australia.

Table 1: Summary of classification rules for software-based medical devices

		Diagnosing/screening and/or specifying or recommending treatment/intervention for a disease or condition	
		Provides information to an individual	Provides information to a health professional
Risk to individual or public health	**Death/severe deterioration/high public health risk**	III	IIb
	Serious disease or condition/otherwise harmful/moderate public health risk	IIb	IIa
	Any other case	IIa	I
		Monitoring the state/progression of a disease or condition	
	Immediate danger to a person/high public health risk	IIb	
	Other danger to a person or another/moderate public health risk	IIa	
	Any other case	I	
		For providing therapy through provision of information	
	May result in death/ severe deterioration	III	
	May cause serious harm	IIb	
	May cause harm	IIa	
	Any other case	I	

The problem

Advances in computing technology in the last two decades have resulted in lowered costs and increased access to powerful computing platforms with more software applications being developed for use in the health field. This has given rise to the so-called 'digital health environment' which is rapidly evolving and includes many new medical device software products, and many health-based products which are crossing and/or blending traditional boundaries of therapeutic product definitions.

As a consequence, the boundary for regulated software products is becoming more difficult to identify, a situation that has caused therapeutic goods regulators around the world to consider or to implement changes to their frameworks to address uncertainty.

In addition, feedback from consultation on the regulation of software indicated that there was confusion over what was considered a medical device, and that it was important to clarify this in consultation with stakeholders prior to the commencement of the regulatory changes.

This consultation

The Government has asked us to consider measures that would clarify the boundary for software-based products that are captured under the regulatory framework for medical devices in Australia, and to ensure that sponsors and manufacturers of software-based products are not subject to unnecessary regulatory oversight.

In considering what could potentially be carved out from regulation we propose the following principles:

- 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)

Please note

IVD medical device related software products (such as laboratory information management systems etc.) will also be considered in this consultation.

Your feedback

Are you a patient, manufacturer, sponsor, healthcare provider, industry representative body, consumer advocacy group, scientist, researcher, or other interested party?

We seek your views on a proposal to carve-out certain software-based products from regulation by the TGA. Please refer to the section below*: What we invite you to do*

Approaches by other regulators to "carve-out"

We have analysed the approaches taken by comparable overseas regulators in order to identify possible approaches to carving out certain software from regulation, including:

- Australia (AU), Canada (CA), European Union (EU), GHTF/IMDRF (GI), Japan (JP), Singapore (SP) and the United States (US)

There is considerable alignment across the various frameworks in terms of scope and interpretation of what is, and what is not, considered to be a medical device.

In most cases, the most common approach undertaken by international regulatory jurisdictions to clarify what their respective frameworks should capture has been the publication of guidance material. Health Canada has published a guidance document on software-based medical devices, including what is considered in and what is considered out of scope of the Canadian regulatory framework. The EU has also release guidance material on the regulation of software.

Some regulators have identified some software that, while meeting the definition of medical device, are considered to be posing no potential for significant harm to a patient, user, or others. This might include, for instance, certain types of software used by consumers to manage selected ongoing conditions or chronic diseases, such as:

- software intended to help patients manage stress for mental health by providing daily motivational tips to promote a positive mental outlook, directing mindfulness activities.

Some software-based products may be subject to other systems of regulatory or pseudo-regulatory oversight. Thus, there may be other adequate controls in place that might mean that TGA regulation of certain types of software-based products is deemed unnecessary even where they meet the definition of a medical device in the Act. In the case of the US, the US Food and Drug Administration (US FDA) exercises enforcement discretion powers such that some types of software, even when medical devices under law, are not made subject to regulatory enforcement by the regulator.

Carve-out mechanisms

Under the Act, there are two means for legally carving out certain software-based products either from the scope or from selected requirements- *exclusions* and *exemptions*.

An **exclusion** means that the specified products are **not subject to regulation by the TGA.** Specified products may be excluded for all applications or, alternatively, only when used, advertised, or supplied in a specified manner for a particular purpose.

Excluded products would be:

- not able to be included in the ARTG;
- not required to be assessed in any way by the TGA before they are made available in Australia; and
- not monitored for ongoing safety by the TGA after they are made available.

Suppliers of excluded products would also not be required to report adverse events associated with their product and the TGA would be unable to take regulatory action such as a recall or issuing a hazard alert if there is a problem with the product. Advertising of excluded goods is

also not subject to the Therapeutic Goods Advertising Code. However, the products are still subject to relevant consumer laws.

Before making a determination to exclude goods from the regulatory scheme, the Minister (or his delegate) must have regard to:

- whether it is likely that the specified product, if not regulated under the Act, might harm the health of members of the public;
- whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by TGA legislation to regulate the specified product; and
- whether the kinds of risks from the specified product to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.

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).

Sponsors of exempted devices still need to ensure that the products meet the relevant essential principles for safety and performance and must report all adverse events to the TGA. The TGA is also still able to take regulatory action if the device is being advertised in contravention of the advertising requirements under TGA legislation.

Proposed carve-out principles

The clarification of what is in and what is out of scope of the medical devices regulatory framework can be achieved via an exclusion and/or exemption (or a combination or both).

Consideration will be given as to whether an exclusion or exemption would be appropriate for the carve-out of certain software-based products in circumstances where:

- it can be demonstrated that there are already adequate (or similar) alternative mechanisms in place for oversight for software-based products;
- any risks associated with their use and performance (e.g., risk of misdiagnosis or inappropriate treatment) can be appropriately mitigated

A carve-out would not be required for software-based products that do not meet the definition of a medical device and can be addressed through guidance.

Clarification of what is and isn't in scope through interpretation of the regulatory definition of a medical device

To assist in understanding what software-based products could potentially be considered for carve-out from the regulations, it is important to first clarify what types of software products would be considered a medical device and what would not be.

Software products are a medical device when they are intended to perform a medical device function (see legislative definition at Appendix 1). These functions include:

- providing a diagnosis;
- analysing patient data to screen for a disease;
- specifying a treatment;
- providing information for monitoring a disease or patient parameters;
- controlling a hardware medical device; or
- providing therapy.

Software for the following intended purposes is considered to be a medical device as per the definition:

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

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

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

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

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

- **Administrative support of a health care facility**, including the 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**, including real time prescription monitoring or electronic prescription exchanges. Examples include software that is intended to provide electronic medication chart, electronic prescribing and support healthcare professionals to order, check and record administration of medicines; and software that is intended to provide secure and safe transmission of prescription information between doctors and pharmacists.
- **Medication/adherence (treatment regimens)** - Examples include; software intended to provide information on drug–drug interactions; and software intended to help patients improve medication adherence.
- to **serve as electronic patient records**, including patient provided information to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart so long as:
  - such function is not intended to interpret or analyse individual patient records, including medical image data, for the purpose of diagnosis, prevention, treatment etc. of a specific disease or condition.
- **Electronic patient record keeping** – examples include software that that helps individuals interact with these records, or enables individuals to organise their health information (this includes manual patient recording of blood glucose, asthma attacks, blood pressure, etc.).
- **Clinical workflow and support** - software to support health professional. Examples include software that is intended solely to display or print medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical-practice guidelines).
- **Used for education, training, or guidance** - Examples include; online textbooks, clinical guidance materials (including decision trees) for health professionals, software intended to

help patients to self-manage diseases/ conditions through the provision of educational information.

- for **transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results**. Findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyse clinical laboratory test or other device data, results, and findings. This includes secure messaging software.
- **Processing tools** (transferring, storing, converting formats, archiving, encrypting data) – Data platform that is intended to provide secure information storage and exchange data between applications.
- **Communication tools** (e.g., between healthcare professionals, patients, pathology labs). Examples include; telemedicine, video-conferencing software; and an online health platform that is intended to help patients to find healthcare providers, book appointments and obtain online consultations via tele-conferencing.
- **Health information management/database systems –** Examples include; a database (including search and query functions) intended to be used for storing health-related information and records; an application that provides library functions such as the retrieval of records by matching record metadata against record search criteria; and software that is intended to electronically receive, collect, store, transform and distribute data within or between healthcare facilities to support the administrative and clinical activities. Software intended to be used in hospitals to aggregate information from different systems.
- for **maintaining or encouraging a healthy lifestyle** – Health and lifestyle apps including software intended to record fitness, wellness or to encourage a healthy diet or lifestyle without claiming to treat, prevent, manage, or predict susceptibility or risk of contracting a disease, condition, etc.; or to provide rehabilitation for a disease, condition etc.
- Software intended to extract **data from clinical trial or patient records** for population-based analyses.
- **Monitoring or management of Health IT systems –** Monitoring uptime, cyber threats, performance, load on networks, servers, etc. in health environments (unless as an accessory to a medical device).
- **Medi-alerts** an example might be fall detectors not intended for the purpose of monitoring a disease or condition (such as Multiple Sclerosis).
- **Standard IT equipment where the manufacturer is not making any therapeutic claims –** Desktops, monitors, accessories; tablets, mobile phones, smart watches. (Note that if a manufacturer takes commodity hardware and packages it with claims about having a therapeutic purpose then it becomes a medical device in most jurisdictions. It is the intended purpose/use—not the form—in which something is presented that is the determiner of whether something becomes a medical device or not.)
- **Travel medicine tools -** Software intended to provide up to date travel vaccination advice and individualised vaccination scheduling.
- **Predictive analysis –** Software intended to predict whether a person ends up in an emergency department in the next 30 days by extracting information from the patient's health records.

- **Archetype editor –** Software intended to be used by clinicians to develop and edit archetypes for use in both point-of-care and research settings.

Software that could be potentially excluded or exempted from regulation

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

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

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

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

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

Software used by consumers

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

Patient information and health management:

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

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

Software used by health professionals

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

Software that analyses a group of patients for common trends or diagnostic indicators e.g. breast density and cancer propensity could be excluded or exempted, while software that performs patient-specific analyses/ diagnoses/ treatment recommendations – e.g. radiotherapy dosage plan, would be regulated as a medical device

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

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

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

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

- Lab Support Software that is intended to be used in an accredited pathology laboratory

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

- Clinical Decision Support Software

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.

What we invite you to do

In your submission, we ask you to consider and respond to the questions below, and to provide comments on the issues outlined in this consultation paper.

Questions

- **What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?**
- **What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?**

  Please provide details:

  of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products; or

  describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.
- **Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?**

Please refer to How to submit your feedback to the TGA.

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

Please submit your feedback directly to the TGA by email: devicereforms@health.gov.au.

Enquiries

Please direct any questions or queries relating to the consultation to: devicereforms@health.gov.au

Please note

Before providing feedback, it is important to read the explanatory material that follows.

Next steps

Following closure of this consultation the TGA will review the feedback received on what types of software-based products could potentially be carved out from regulation, if appropriate, for what purposes. We will discuss areas of concern or requests for further clarification with relevant stakeholders.

Consideration also needs to be given to how consumers would view the prospect of using medical device apps that are not regulated by the TGA. Many clinicians and healthcare systems also rely on inclusion in the ARTG as an indication of safety quality and performance of the device.

Before a Ministerial decision can be made to either exclude or exempt a software-based products, the TGA will need to consider whether there are any policies, standards, regulatory frameworks or accreditation systems already in place that would negate the need for the TGA to regulate certain products.

A summary of the submissions and carve-out options for certain software-based products will be provided to the Minister for consideration.

Appendix 1 - The legal definition of a medical device

Therapeutic Goods Act (1989) **section 41BD:**

(1) A ***medical device*** is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).

(2) For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, material or other article (the ***main equipment***) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:

(a) the labelling on the main equipment;

(b) the instructions for using the main equipment;

(c) any advertising material relating to the main equipment;

(d) technical documentation describing the mechanism of action of the main equipment.

(2A) The Secretary may, by notice published in the *Gazette* or on the Department's website, specify a particular instrument, apparatus, appliance, material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument.

(2B) The Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, materials or other articles for the purposes of paragraph (1)(ab).

(3) The Secretary may, by order published in the *Gazette* or on the Department's website, declare that a particular instrument, apparatus, appliance, material or other article,

or that a particular class of instruments, apparatus, appliances, materials or other articles, are not, for the purposes of this Act, medical devices.

Note: A declaration under this section does not stop articles from being therapeutic goods.

(4) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on the Department's website or on such later day as is specified in the order.

The *Therapeutic Goods (Articles that are Medical Devices) Specification 2014* also specifies that instruments, apparatus, appliances, materials or other articles (whether used alone or in combination, and including the software necessary for their proper application) that:

(a) are intended by the person under whose name they are or are to be supplied to be used for the examination of a specimen derived from a human body for the purpose of:

(i) predicting the susceptibility or predisposition of persons to a disease or ailment; or
(ii) testing for pregnancy in persons;

are also captured as medical devices.

Appendix 2 - New classification rules

Schedule 2 to the ***Therapeutic Goods (Medical Devices) Regulations 2002*** sets out the classification rules for medical devices other than IVD medical devices. New rules have been introduced for the classification of programmed and programmable medical devices, and software that is a medical device (PPSMD). The new rules cover software-PPSMD used for:

- Diagnosing and screening for a disease or condition
- Monitoring the state or progression of a disease, condition, etc.
- Specifying or recommending a treatment
- Providing therapy (via provision of information)
- Patient images and anatomical models (introduced as part of the personalised medical device reforms)

The new rules are summarised below.

1. Products intended to provide a diagnosis of, or to screen for diseases or conditions:

- Class III – that may lead to the death of a person or to a severe deterioration of a person's health without urgent treatment, or that may pose a high risk to public health
- Class IIb – a serious disease or serious condition or a disease or condition which may pose a moderate risk to public health
- Class IIa – other cases

2. Products intended to provide information to a relevant healthcare professional in relation to a disease or condition:

- Class IIb – if it may lead to the death of a person or to a severe deterioration of a person's health without urgent treatment, or that may pose a high risk to public health
- Class IIa – a serious disease or serious condition or a disease or condition which may pose a moderate risk to public health
- Class I – other products

3. Products for use for monitoring the state or progression of a disease or condition by processing data in order to provide an output in the form of information about the state of a disease or condition, or about patient parameters.

- Class IIb – If such products are intended to provide information that could indicate that the person, or another person, may be in immediate danger or that there may be a high risk to public health
- Class IIa – If such products are intended to provide information that could indicate that the person, or another person, may be in another form of danger (i.e. in danger but not immediate danger) or that there may be a moderate risk to public health
- Class I – other products

4. Products intended to specify or recommend a treatment or intervention

- Class III – in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may lead to the death of a person or to a severe deterioration of a person's health or may pose a high risk to public health
- Class IIb – in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may otherwise be harmful to a person or may pose a moderate risk to public health
- Class IIa – other products

1. Products intended to be used to **recommend a treatment or intervention to a relevant health professional** for the purposes of assisting or enabling the health professional to make a decision about the treatment or intervention.

- Class IIb – if such products are intended to recommend a treatment or intervention to a relevant health professional in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may lead to the death of a person or to a severe deterioration of a person's health or may pose a high risk to public health
- Class IIa – if such products are intended to recommend a treatment or intervention in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may otherwise be harmful to a person or may pose a moderate risk to public health
- Class I – other products.

2. Products to provide therapy to a person through the provision of information – if in relation to therapy

- Class III – that may result in the death or a severe deterioration of a person's health,
- Class IIb – may cause serious harm to the person
- Class IIa – may still cause harm to the person
- Class I– other products.

3. Medical devices that record patient images or that are anatomical models etc. that are used in the diagnosis or monitoring of a disease or condition, injury or disability or used in the investigation of the anatomy or of a physiological process.

- Class IIa – that are used to record patient images (acquired through a method that relies on non-visible energy, e.g., X-rays)
- Class IIa – a virtual (or physical) anatomical model
- Class IIa – a programmed or programmable medical device, or software that is a medical device used to create a virtual anatomical model

Note, this was a pre-existing classification rule which was amended to include medical devices intended for creating virtual anatomical models. This change was made in relation to the reforms for the regulation of personalised medical devices.

Examples of software that is currently regulated as a medical device, but will be reclassified under the reforms include:

- Software for patient image processing for the purpose of screening for a disease or making a diagnosis
- Apps that can control or adjust a hardware medical device, such as an implanted spinal stimulator, through Bluetooth or WiFi features
- Software that specifies a therapy such as radiation therapy for treating cancer
- Software that analyses physiological signals to monitor a disease or condition, for example an app that processes data from a mobile ECG device to detect heart arrhythmias

Reference information

Europe

The EU MDR 2017/745 introduced new classification rules that align with the IMDRF principles and are summarised in the table below (for further detail refer to EU MDR 2017/745, Annex VIII 6.3, Rule 11).

State of healthcare situation or condition	Provides information used to take decisions for diagnosis	Provides information used to take decisions for treatment	Monitors physiological processes (vital/non-vital)
Critical (Vital)	Class III	Class III	Class IIb
Serious (Vital)	Class IIb	Class IIb	Class IIb
Non-serious (non-vital)	Class IIa	Class IIa	Class IIa

* The EU 2017 MDR is silent on:

- devices that provide therapy through the provision of information so these default to Class I.
- public health risks related to diagnosis or monitoring so these devices are likely to be Class I or IIa unless there is an associated individual risk.

The European Commission Guidance for Software Regulation . In this document, the EU has mapped its classifications against the IMDRF principles in the following table.

USFDA

Clinical Decision Support Software – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

Changes to Existing Medical Software Policies Resulting from Section 3060 of the *21st Century Cures Act* - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act

Policy for Device Software Functions and Mobile Medical Applications - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications

Canada

Health Canada, Guidance Document: Software as a Medical Device (SaMD): Definition and Classification Guidance Document: Software as a Medical Device (SaMD): Definition and Classification - https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html#a2.1

IMDRF

International Medical Device Regulators Forum - "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations - http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf

International Medical Device Regulators Forum – Clinical Evidence for Software - http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf

International Medical Device Regulators Forum - Quality Management Systems for Software - http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf

Version history

V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Surveillance Branch	March 2020

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 #