Australian Government

Department of Health

Therapeutic Goods Administration

# Consultation: Regulation of software, including Software as a Medical Device (SaMD)

February 2019

TGA Health Safety Regulation

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# Contents

# Introduction

The Australian Government is undertaking a significant program of reform to the regulation of medicines and medical devices in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates these products, and is responsible for implementing the Government's reforms.

> **The purpose of this consultation** is to seek feedback on how software, including Software as a Medical Device (SaMD), is regulated in Australia.
>
> Consultation questions and information on how to make a submission are provided on page 15& 16.

This document is focused on regulatory reforms for medical device software, including software that functions as a medical device in its own right (SaMD) and the impact of these reforms. It does not cover the technical considerations for designing, manufacturing and testing such devices.

Software is regulated by the TGA under the existing medical device framework; however, advances in technology, including the emergence of 'apps', are not adequately covered in the current scheme.

The regulatory changes proposed in this document only apply to regulated software products. The term SaMD refers to software that functions on a general computing platform, such as a laptop computer, smartphone or tablet, **and** that has an intended purpose consistent with the definition of a medical device[1]. Many health and lifestyle apps are not SaMD, and are therefore not subject to regulation by the TGA.

# Background

Medical device software existed at the time the Australian regulatory framework for medical devices was adopted in 2002; however, at that time the development and use of software for medical purposes was very different than today. Software at that time was still largely developed and published by traditional medical device manufacturers and mainly was embedded in, or controlled, physical medical devices. Stand-alone software that could inform, drive or replace clinical decisions, or that could directly provide therapy to a patient, was not considered.

Smartphones and tablets have become ubiquitous. This means that many people carry at least one highly capable computer with them everywhere they go. Improvements in networking mean that consumers also have access to high powered central computers through the 'cloud'. Perhaps most importantly, software is now easily developed and published by individuals, through one of the many app stores or their own websites.

These rapid advances in computing technology and software production have led to an explosion of the number of SaMD products on the market. It has also resulted in change to the risk profile of SaMD products. Fifteen or twenty years ago it was not possible for a patient to carry a high-powered computer in their pocket with the potential to monitor, diagnose or treat disease. Today, this is becoming reality.

[1] *Therapeutic Goods Act 1989* - section 41BD. Further information is available in Appendix 1.

# The problem

There are three key issues regarding the regulation of software, including SaMD, under the current medical device regulatory framework in Australia.

The first issue is that the **classification rules** under the current regulations do not adequately consider the potential for SaMD products to cause harm to patients.

A second issue is that **software can now be downloaded by the user directly** from the publisher, without the need for an importer or retailer. This means that there is no entity in Australia that is monitoring the safety and performance of directly-imported SaMD; and there is no-one accountable to the regulator for post-market actions.

The third issue with the regulation of medical device software is the **lack of clarity in the regulatory requirements** for demonstrating its safety, quality and performance.

# Do the Regulations need to change?

More and more SaMD products are entering the Australian market, and more and more of them present a moderate or high risk to patients and consumers. This includes SaMD that relies on algorithms using artificial intelligence (AI) or Machine Learning (ML). However, the current regulations do not adequately address software that provides information used to diagnose or treat a medical condition, or that directly provides therapy through patient interaction.

The current regulatory framework ensures that medical devices that are classified as moderate to high risk receive more regulatory scrutiny than those classified as lower risk before they are supplied in Australia. It also requires that higher risk devices have more ongoing scrutiny, when they are on the market. Software incorporating AI or ML changes over time as it 'learns', making ongoing performance monitoring particularly important; but even these are classified as Class I under the current regulations.

Another area for potential regulatory reform is the ability for SaMD products to be imported into Australia in large volumes without being included in the Australian Register of Therapeutic Goods (ARTG) by an Australian sponsor. Under the current regulations, this is only considered allowable for SaMD if the SaMD products are imported for individual use using the exemption for personal importation of therapeutic goods.

Personal importation occurs when:

- an individual arranges from within Australia for a therapeutic good to be sent to them (including through the internet) from an overseas supplier or family/friend; and
- the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person.

SaMD that is not included in the ARTG does not undergo any scrutiny of its supporting evidence including the certification of the manufacturer where required. In addition, it cannot be monitored for ongoing safety, quality and performance; and post-market actions such as recalls or suspension cannot be enforced where necessary for public health and safety. With the easy access to technology today, millions of Australians could be downloading and using a SaMD product. The personal importation provisions were not intended to enable the importation of therapeutic goods in large volumes without TGA oversight.

The regulatory requirements for safety and performance of medical devices are specified as essential principles[2] which specify requirements that all medical devices must comply with to be supplied in Australia. However, these principles do not explicitly mention software, which creates uncertainty around the requirements for SaMD. Adding new essential principles, or making changes to existing ones, would help clarify the requirements for SaMD products to be supplied in Australia.

It is proposed to introduce appropriate regulatory controls and clarification for this emerging field of medical device software, including SaMD.

# Proposed regulatory amendments

## Summary of proposed changes

The following changes to better regulate software, including SaMD, are proposed for introduction. The proposed changes will, wherever possible, be harmonised with international best practice, and it is proposed that the transition period will coincide with the transition in Europe to the Medical Device Regulation 2017/745. The proposed changes are:

- ensuring the classification rules for medical devices will **appropriately classify SaMD products according to the potential harm they could cause to patients**
- **excluding SaMD products from the personal importation provisions** in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) so that SaMD products will be required to be included in the ARTG and have an Australian sponsor
- ensuring the **essential principles for medical devices include clear and transparent requirements for demonstrating the safety and performance of SaMD and other regulated software**.

## Details of proposed changes

### 1. Changes to the classification rules

Medical devices are classified according to the potential for them to cause harm. The lowest risk devices are Class I and do not require any third party oversight to be included on the ARTG. The other classifications are Class Is, Class Im, Class IIa, Class IIb and Class III, the latter of which represents the highest risk category and requires the highest level of third party scrutiny.

Medical devices are classified using the rules in Schedule 2 of the Regulations[3]. However, the classification rules currently only consider the possible harm caused by a physical interaction of a medical device and a human. Software as a Medical Device does not have this direct physical interaction. The risks posed by software are more along the lines of incorrect calculation, incorrect diagnosis, or an incorrect decision for a treatment modality, which may subsequently cause great harm. For this reason, the classification of software under the current framework is often not in accordance with the level of risk it poses.

[2] Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1.
[3] Therapeutic Goods (Medical Devices) Regulations 2002

Regulation 3.3 (5) includes the only specific rule for classifying software in the current framework:

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

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

As technology advances there are more and more SaMD products that present a moderate or high risk to patients. These may include software apps that calculate medicine doses, or that directly make a diagnosis. Some examples are apps that make a diagnosis through analysis of electrocardiogram (ECG) data, or that make a diagnosis through the application of artificial intelligence or machine learning in the analysis of skin images for detecting melanoma. Such devices should be subject to third party oversight that is commensurate with the risk they represent to patients.

## What would change?

It is proposed to classify SaMD having consideration for international best practice. New requirements for software are emerging in different jurisdictions including Europe and the USA. In addition, the International Medical Devices Regulators Forum (IMDRF) has established internationally aligned regulatory principles for software as medical device. It is planned to use the factors identified by IMDRF for risk categorisation of software to classify SaMD products in Australia. This means that rules would be written that consider both the seriousness of the situation or condition where the SaMD is used, and the significance of the information being provided by the SaMD.

IMDRF has consulted internationally on SaMD and produced recommendations for its regulation. The IMDRF guidelines for risk categorisation of SaMD[4] identify the following key factors that affect risk:

- Significance of the information provided by the SaMD to the healthcare decision
- The context in which the information will be used
- The state of the healthcare situation or condition.

For example

- A SaMD that provides information based on patient measurements to inform a physician who is making a decision about a non-serious disease would remain Class I.
- In contrast, a SaMD that is directly diagnosing a critical medical condition would be Class III.
- A possible example of a Class IIa might be a SaMD that treats a non-serious condition, and SaMD that diagnoses a serious condition might be Class IIb.

[4] IMDRF Technical Document - Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF/SaMD WG/N12FINAL:2014)

The EU MDR 2017/745 has introduced the following new classifications for software (summarised below):

Software that provides information to be used in making decisions for diagnosis or treatment is:

- Class III if the decisions have an impact that may cause death or an irreversible deterioration of a person's state of health
- Class IIb if the decisions have an impact that may cause a serious deterioration of a person's state of health or a surgical intervention
- Class IIa in any other case

The European rule is in accordance with the IMDRF recommendations; however, it does not provide enough detail to capture the different risk categories of SaMD identified by IMDRF.

More detail is required in the Australian classification rule to close any gaps, which will promote clarity and consistency, and the following approach is proposed:

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

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

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

- Specify a treatment or intervention that will be administered without further consideration (e.g. – the patient will inject the amount of insulin calculated) where:
  - the treatment or intervention, or its absence, could result in death or debilitation. The device is Class III.

  - the treatment or intervention, or its absence, could be harmful. The device is Class IIb.
  - the treatment or intervention, or its absence, is unlikely to cause harm. The device is Class IIa.
- Recommend a treatment or intervention for a clinician to decide and administer. The device is Class IIa.

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

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

### What would this mean?

Introducing new classification rules that apply to SaMD would mean that some SaMD products would be Class IIa, Class IIb and Class III medical devices, and would therefore be subject to third party oversight through application of the conformity assessment procedure required for those classes. This would affect new and existing SaMD.

Existing SaMD products that are currently included in the ARTG as Class I would need to be re-classified. This may result in a requirement for their sponsors or manufacturers to hold additional evidence to remain on the ARTG. This re-classification of existing SaMD products would be subject to a transition period when the new regulations are introduced.

## 2. Requiring SaMD to be included in the ARTG

Currently SaMD products that are developed overseas and made available online are likely to be captured by the exemption for personal importation provided in the legislation. This exemption allows medical devices, which are not included in the ARTG, to be imported for personal use.

The result is that these products do not have a sponsor in Australia, which means there is no-one that is accountable to the TGA for the quality, safety or performance of these products, and no-one is monitoring the products' performance in the Australian market (e.g. receiving and acting on complaints or adverse events). The TGA is limited in its ability to regulate these products without a sponsor or an ARTG entry.

The personal importation provisions are intended to allow for the importation of a small number of products, for a short period of time (usually three months). However, today most software is supplied by download, often from an overseas supplier. This means that users, patients and consumers can download their own personal copy of the software and use it, in many cases for many months or years. Although each individual is personally importing their own copy, millions of Australians may have done so. This means that a SaMD product may be bypassing regulation by the TGA, even though it may be being supplied to millions of Australians. Because these provisions bypass the requirements for safety, quality and performance, and post-market monitoring, normally applied to medical devices that are

supplied in Australia, they are not intended to enable the importation of therapeutic goods in large volumes without TGA oversight or long-term use of imported medical devices.

### What would change?

It would be proposed to government that the Regulations be amended so that all SaMD products are required to be included in the ARTG by excluding them from the provisions for personal importation.

This change would mean that all SaMD products would require a sponsor in Australia before they can be supplied in Australia, including through internet download.

This would ensure that there is an Australian entity responsible for monitoring the device and reporting to the TGA. It would also mean that SaMD products developed and distributed from overseas will not be able to bypass the requirements for medical devices in Australia, for example compliance with the essential principles. Under this potential change to regulation, there would be better visibility of SaMD products being supplied in Australia, as all would be included in the ARTG.

### What would this mean?

This is expected to have limited effect on Australian developers of SaMD products, because their products are not being imported to Australia, they are manufactured here. The Australian developer who is supplying their products in Australia is already required to be a sponsor under the legislation.

This proposed change is expected to impact overseas developers who currently supply SaMD to Australia by download from an App store or other online system. Under the proposed change, these developers would require an Australian sponsor, and inclusion of their SaMD in the ARTG. Mechanisms for adherence to these requirements may include exploring agreements with large scale SaMD providers (App stores) that have an Australian presence. Adherence to requirements of Australian access for non-compliant overseas SaMD providers will also be investigated.

## 3. Changes to the essential principles

The requirements for safety and performance of medical devices are expressed under the current regulatory framework as the essential principles[5]. These are "principles" rather than "rules" because of the vast diversity of medical devices, in terms of form, function, intended purpose, composition, manufacturing method, etc., that must be accommodated under the framework. Internationally recognised standards for devices are often used to demonstrate that a device conforms to the relevant essential principles.

The essential principles do not specify particulars such as which standards must be complied with, or what kind of testing must be undertaken, what kinds of packaging must be used, etc. This means that the manufacturer has the freedom to determine how they will demonstrate compliance, using a risk mitigation strategy. Because of the way they are written, the essential principles allow flexibility to regulate all medical devices, including new technologies.

However, the essential principles do not currently include any explicit mention of software. Thus, it may not be clear to designers and manufactures what is required for SaMD products to comply with the Australian legislation. Changing the essential principles will improve clarity for software designers and developers, while still maintaining the flexibility for the regulations to capture new and emerging technologies.

[5] Therapeutic Goods (Medical Devices) Regulations 2002 – Schedule 1

### What would change?

It is proposed to add the following points of clarification into the essential principles:

- the features, capabilities and risks of the computing platform be taken into account during design and manufacturing
- the cyber security risks associated with network connectivity be minimised
- that software be designed and produced using best practice software engineering principles
- that medical devices indicate when critical features and connections are or are not enabled, and provide appropriate alarms
- best practice cyber security principles be used regarding the risk of unauthorised access to the device
- medical devices be designed to facilitate software updates, and information about the clinical risk of an update is provided to the user
- that requirements relating to the computer platform, operating system, accessories and network security be provided in the instructions for use

Some of these clarifications can be achieved by making changes to existing essential principles, but it is expected that one or two new essential principles, specifically for software, may be needed.

### What would this mean?

Much of what is proposed to change represents good software development and security. In many cases these things are already being done by developers and manufacturers.

The proposed changes to the essential principles will make the expectations for demonstrating compliance for software products more transparent, and will allow for consistent enforcement of the requirements. This will make it easier for developers and manufacturers to understand what the minimum requirements for SaMD are.

In many cases there will be some additional work for developers and manufacturers to formalise what they are already doing and document the evidence for assessment by a third party. However, this is the same requirement as for other medical devices. In some cases, new quality management and development practices may have to be put in place to demonstrate compliance.

For patients and users, there will be more information consistently available on how to safely and effectively use SaMD products. The nature of SaMD means that it is more dependent upon users and consumers maintaining the computer platform and networks appropriately, and currently this information is not always easily available, meaning that SaMD products may be inadvertently used outside their intended environment.

# Benefits of the proposed changes

The proposed regulatory changes are intended to align with the objectives for regulating software, including software as a medical device, which are:

1. minimising public health and safety risks
2. maintaining consumer confidence in the regulation of medical devices
3. aligning, as far as possible, with international best practice

4. minimising unnecessary regulatory burden.

The proposed changes are expected to provide benefits to patients and consumers by ensuring that the appropriate amount of third party oversight is in place and commensurate with the level of patient harm that a medical device could cause. It will also mean that the level of assessment of moderate and high risk SaMD products will be consistent with the assessment applied to other medical devices of similar risk.

Additionally, the proposed changes are expected to provide benefits to the regulated industry sector because the requirements for SaMD products will be clearer. Furthermore, some devices currently exempt from inclusion in the ARTG will require inclusion and may also require third party assessment. This provides a degree of public confidence in those products and may facilitate reimbursement. The changes will also level the playing field for manufacturers by making the SaMD classification levels and requirements clearer and more consistent. Manufacturers of SaMD products who are currently complying with the essential principles will not be unfairly competing with manufacturers who may be cutting corners in the absence of regulatory oversight.

In addition, these changes are moving Australia's regulation of SaMD towards international harmonisation.

# Regulatory impact of the proposed changes

As part of the consideration of potential changes presented in this document, a regulatory impact assessment may be required. This will assist the government's decision-making process for the proposal. Your input to this process will assist us with understanding the benefits and potential burdens of the proposed changes, and will help to ensure that the impact analysis is as accurate as possible.

Many new regulations or changes to existing regulations need to have the regulatory costs imposed on businesses, community organisations and individuals quantified. When quantifying the regulatory cost of the proposed amendments, the following compliance costs are included in its calculations:

- administrative costs – costs incurred by regulated entities primarily to demonstrate compliance with the regulation (usually record keeping and reporting costs); these may include:
  - time taken for sponsors/manufacturers to become aware of definition changes and decide if they need to make any changes
  - time taken by sponsors to educate/familiarise themselves with the conformity assessment procedure i.e. reading new information/guidance (this would be a one-off cost)
  - time taken by sponsors/manufacturers to complete the process.
- substantive compliance costs – costs incurred to deliver the regulated outcomes being sought (usually purchase and maintenance costs); these may include:
  - changes to record management systems that will be needed to demonstrate compliance
  - any equipment that will need to be purchased and maintained.

The approach used by Australian departments and agencies excludes the following costs from its calculations:

- direct financial costs i.e. fees and charges
- indirect costs i.e. changes in market structure and competition impact
- opportunity costs
- business-as-usual costs
- noncompliance and enforcement costs
- government to government costs.

Further information on the quantification of regulation is provided in the Australian Government's Regulatory Burden Measurement Framework Guidance Note.

# Framing your feedback to us

When framing your feedback, it may be useful to consider the practical implications of the new requirements for your situation as well as for other stakeholders.

## For manufacturers of SaMD

Manufacturers of SaMD are required to have an established quality management system and to apply the conformity assessment procedures, according to the classification of their medical devices. This means, for devices that are classified above Class I, conformity assessment evidence from a recognised third party (such as the TGA or a notified body) will be required. The manufacturer will be required to apply for this evidence and, once received, maintain its currency through complying with post-market requirements such as annual inspections by the issuing agency.

Australian manufacturers of SaMD will also be required to include their medical devices in the ARTG and to comply with the requirements for maintaining the inclusion.

## For sponsors of SaMD

Sponsors of SaMD will be required to include these medical devices in the ARTG, and to comply with the requirements for maintaining the inclusion.

## For manufacturers of SaMD that is already included in the ARTG

Manufacturers of SaMD that is already included in the ARTG will need to re-assess the classification of their product(s) according to the proposed new classification rule for SaMD. This may result in some products being classified at a higher level, requiring the manufacturers to hold conformity assessment evidence from a recognised third party (such as the TGA or a notified body).

Australian manufacturers of SaMD will also be required to lodge any new third party conformity assessment evidence with the TGA and, to submit new applications for inclusion in the ARTG according to the classification of the SaMD product(s).

### For sponsors of SaMD that is already included in the ARTG

Sponsors of SaMD that is already included in the ARTG will need to re-assess the classification of their product(s) according to the proposed new classification rule for SaMD. This may result in some products being classified at a higher level. In this case, sponsors will be required to ensure the manufacturers of the products they represent hold conformity assessment evidence from a recognised third party (such as the TGA or a notified body) and, to lodge this evidence with the TGA. They will also be required to submit new applications for inclusion in the ARTG according to the classification of the SaMD product(s).

# Consultation

One of the challenges in regulating SaMD is that many of the developers are not familiar with medical devices, regulation, or the TGA. This is because of the way software is developed and published today. SaMD products can be readily developed by small businesses and individuals in isolation and published through an app store or website. As a result, many SaMD developers may not even realise that their product is regulated. This means that for SaMD, the TGA needs to extend consultation beyond traditional communications channels and established medical device manufacturers.

## Consultation completed in 2018

The TGA engaged the Commonwealth Scientific and Industrial Research Organisation (CSIRO) in 2018 to map the SaMD landscape in Australia. Through this work CSIRO reached out to many in the SaMD community in Australia, including surveying and interviewing those who are currently supplying SaMD, developing SaMD or are likely to begin to develop SaMD, and researched their level of regulatory engagement. This work raised awareness with stakeholders of the intention to carry out the current consultation, and also provided preliminary feedback to us on the challenges faced by SaMD stakeholders. Further, the research provided a foundation for the TGA's engagement strategy on this subject.

## This consultation - What we invite you to do

In order to obtain additional feedback, we invite stakeholders to provide their comments on the proposals for change. Specifically, your feedback is sought on the suitability and potential impact that any proposed changes to the regulations will have on you or your organisation.

In your submission, we ask you to consider the questions below and to provide comments related to any other matters outlined in this consultation paper. Submissions must be relevant to the proposed changes for regulating personalised medical devices.

**Questions**

1. Do you support the proposal to change the way medical device software is regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?
2. What do you consider to be the benefits and disadvantages of the particular proposals for change?
3. Do you believe there will be any unintended consequences arising from the proposed changes?
4. What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?
5. What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.
6. What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.

## How to submit

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

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au. If you do so, **please ensure your submission is accompanied by a cover sheet**.

**This consultation closes on 31 March 2019.**

## Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

# Appendix 1 – What is Software as a Medical Device (SaMD)?

Australian legislation already has a clear definition of medical device. Any product that meets that legislated definition is regulated as a medical device under the *Therapeutic Goods Act 1989* (the Act). The TGA refers to software that meets the legislated definition of a medical device as Software as a Medical Device (SaMD). This means that in Australia all SaMD is regulated by the TGA, software that is not regulated by the TGA is not SaMD. It is important to note that SaMD relies only upon the computing platform it operates on, and not on any physical accessory or embedded feature (e.g. camera, accelerometer), to achieve its diagnostic or therapeutic purpose.

## Software as a Medical Device

Software products are regulated as medical devices if they fit the definition in section 41BD of the Act.

> 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.

Many types of software meet this definition and are therefore regulated. Some examples of SaMD 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.

SaMD may be used with or in different computing platforms such as:

- Computers
- Mobile phones
- Tablets
- Virtual or Augmented Reality Platforms

## Health software apps that are *not* medical devices

Many mobile apps are simply sources of information, or tools to manage a healthy lifestyle. The TGA does not regulate health and lifestyle apps, or other software products, that do not meet the definition of a medical device.

## Apps that use accessories connected to, or embedded in, the platform

Some mobile apps require the use of physical accessories that are connected to, or embedded in, the computing platform. These can be sensors that plug into a port on the platform or are wirelessly connected to the platform, or they can be features that are provided in the platform such as speakers or a camera. This results in the combination of software, accessory and the computing platform becoming a medical device.

One example is a glucose meter that reads blood test strips and plugs into a smartphone to display and store the results. In this case, the combination of meter, smartphone and app, is a medical device. The app is regulated as part of the glucose meter device.

## Software that is part of a device

Medical device software that is an integral part of a physical device (for example embedded software or firmware in a cardiac pacemaker) is considered to be part of that device and is not regulated separately.

## Apps that control a medical device

Some mobile apps can control or adjust a medical device through Bluetooth, WiFi or other connectivity features. These apps are not considered to be SaMD; because on their own, they do not usually fit the definition of a medical device. However, they are considered to be accessories to the medical device, making them medical devices themselves under the framework. The current classification rules specify that software that controls another medical device is regulated at the same risk classification level as the medical device it controls.

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Medical Devices Branch, Therapeutic Goods Administration | February 2019 |

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