



# Digital mental health: Software based medical devices

## Who regulates medical devices?

The Therapeutic Goods Administration (TGA) regulates therapeutic goods in Australia, including medicines, biologicals and medical devices.

## When is software a medical device?

Software would generally be a medical device if it is intended to be used for:

- diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury or disability
- alleviation of or compensation for an injury or disability
- investigation of the anatomy or of a physiological process
- control or support of conception.

## What are software based medical devices?

Software means any app, website, program, internet based service or package. It may be on a watch, phone, tablet, laptop or other computer, or part of a hardware medical device. If the software meets the definition of a medical device, it is referred to as a software based medical device; it may also be referred to as Software as a Medical Device (SaMD).

Examples of software based medical devices in digital mental health include:

- apps that provide therapy
- internet based services
- symptom checkers
- suicide prevention apps.

These are also referred to as digital mental health tools.

## How are software based medical devices regulated?

Software based Medical Devices are regulated by the TGA and must be included in the Australian Register of Therapeutic Goods (ARTG), unless they have been excluded.

Changes to the regulations for software based medical devices took effect from 25 February 2021, including a transition period for those already included in the ARTG.

## Regulation of digital mental health software

The first step in determining whether digital mental health software is regulated by the TGA is to determine if it meets the definition of a medical device. If it does not meet the definition, it is not regulated by the TGA.

Under the changes introduced in February 2021 digital mental health tools are excluded from regulation if they are intended for the management of any aspect of mental health, as long as the following conditions are met:

- the software follows established clinical practice guidelines; **and**
- the guidelines are referenced and the reference to them is displayed in the tool; **and**
- the user can clearly view the guidelines.

**If your digital mental health software is a medical device and does not meet ALL of these conditions, it is regulated by the TGA.**

## What is an established clinical practice guideline?

The clinical practice guideline must be widely accepted for use in clinical practice in Australia. Typically, this would mean that health professional representative bodies and/or accredited health care providers, such as hospitals, have published the clinical practice guideline for use in patient care. An example is Anxiety disorders: clinical practice guidelines and associated resources.

## How should the clinical practice guidelines be displayed?

The clinical practice guidelines must be shown in a way that the user can easily see. Incorporating links to guidelines would be acceptable, but only if they are directly available to users (e.g. displayed within an app). Displaying links in a user manual would not be sufficient to meet the exclusion criteria.

## Is a published scientific paper an established clinical practice guideline?

No, the publication must be recognised by a relevant health professional body or an accredited health care facility, such as a hospital. A single paper would not usually indicate that the guideline is established in clinical practice.

## Can you create your own clinical practice guideline?

Creating your own clinical practice guideline for use in your product would not be sufficient to meet the criteria, as the guideline must be widely accepted and established for use in Australia.

## My service uses novel treatment that is still undergoing trials – is it excluded?

Since the treatment is new and still undergoing trials – it would not yet be widely accepted in clinical practice. This means it is not excluded and therefore is still regulated by the TGA.

## Is a paper based questionnaire regulated?

Software that digitises a paper based questionnaire solely for data collection purposes would not be regulated since it would not meet the definition of a medical device. If the software has additional logic beyond the original data collection purpose, it may cross into the scope of medical device regulation, however it

may still be excluded if it satisfies the exclusion criteria for digital mental health tools shown above.

## How does TGA regulation relate to other oversight for digital mental health?

The Australian Commission on Safety and Quality in Health Care (the Commission) has developed an accreditation model for providers of digital mental health services to be assessed against the National Safety and Quality Digital Mental Health (NSQDMH) Standards.

Assessments are scheduled to commence in the second half of 2022.

TGA is working with the Commission and other parts of the Australian Government Department of Health to ensure safety and performance of digital mental health tools and services, while balancing the need to minimise regulatory burden.

## What do you need to do?

- ✓ Check the definition to see if your software is a medical device.
- ✓ Check the exclusion conditions to see if your digital mental health tool is excluded in the Therapeutic Goods (Excluded Goods) Determination 2018 ([legislation.gov.au](https://www.legislation.gov.au)).
- ✓ If your software is a medical device and is not excluded, ensure that you meet all relevant regulatory requirements and apply for inclusion in the ARTG;
- ✓ Ask if you need further guidance or clarification after reviewing the information on our website. You can contact us via our email: [digital.devices@tga.gov.au](mailto:digital.devices@tga.gov.au)

## Links

<https://www.tga.gov.au>  
<https://www.tga.gov.au/medical-devices-overview>  
<https://www.tga.gov.au/regulation-software-based-medical-devices>  
<https://www.tga.gov.au/resource/regulatory-changes-software-based-medical-devices>  
<https://www.legislation.gov.au/Series/F2018L01350>  
<https://www.ranzcp.org/practice-education/guidelines-and-resources-for-practice/anxiety-disorders-cpg-and-associated-resources>  
<https://www.safetyandquality.gov.au>  
<https://www.safetyandquality.gov.au/standards/national-safety-and-quality-digital-mental-health-standards>  
<https://www.tga.gov.au/resource/my-software-regulated>  
<https://www.tga.gov.au/publication/medical-device-inclusion-process>



### More information:

Please contact us at [digital.devices@tga.gov.au](mailto:digital.devices@tga.gov.au)