Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Understanding digital mental health device rules

This guidance helps providers of digital mental health services or products to understand their regulatory obligations.

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Purpose

This guidance is intended to assist providers of digital mental health services or products to understand their regulatory obligations and outlines the key differences between regulation and oversight by the TGA for digital mental health tools and products.

It includes examples of some regulated and unregulated products by the TGA as well as some eligibility requirements for accreditation against the Standards by the Commission.

The general term “digital mental health products” will be used in this guidance.

This complements the guidance on medical device regulation of software more generally and should be read together with the Therapeutic Goods (Medical Devices) Regulations 2002 (the Medical Device Regulations).

The TGA has published a digital mental health fact sheet which this guidance complements and provides more detail on, and there is also Software-based medical devices FAQs.

The Australian Commission on Quality and Safety in Health Care (the Commission) has developed the National Safety and Quality Digital Mental Health (NSQDMH) Standards – a framework to guide safety and quality in digital mental health care. The Commission provides guidance to digital mental health services seeking accreditation to the Standards. This is not a regulated process but may be required by regulators or funding bodies as a requirement to operate or access funding.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Therapeutic Goods (Excluded Goods) Determination 2018

Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

What is in scope of this guidance

This guidance is intended to assist providers of digital mental health services or products to understand their regulatory obligations and outlines the key differences between regulation and oversight by the TGA for digital mental health tools and products. It includes examples of some regulated and unregulated products by the TGA as well as some eligibility requirements for accreditation against the Standards by the Commission.

What is out of scope of this guidance

This guidance does not cover software for use in medical specialisations other than mental health, or other medical device regulation. The TGA website publishes a range of guidance on medical devices and also specifically on software.

There is a large array of consumer and general advice software apps which are not regulated by the TGA or do not fall within the scope of the Commission's NSQDMH Standards – this guidance does not list all of these types of products. For those products that may be regulated, the TGA is responsible for digital mental health products whereas the Commission may provide guidance on safety and quality in

digital mental health services.

What are digital mental health tools and products

This page provides guidance on the regulation and use of digital mental health products. Digital Mental Health products includes both services and tools and devices.

The TGA works closely with the Commission to ensure the safety and performance of digital mental health tools, products and services in Australia while minimising regulatory burden. The different roles of the TGA and the Commission may be summarised as:

- The TGA regulates medical devices and in this case, the software product or tool, such as a website, app or package that delivers the mental health service (unless excluded)
- The Commission develops the Standards used to assess the safety and quality of digital mental health service providers. The Standards apply at the level of the service provider, rather than the specific tool or product.

Providers of digital mental health products need to work out which, if any, requirements they need to comply with and how to get assessed against the appropriate framework.

It is possible that both frameworks may apply. Accreditation to the Standards (via the Commission) is a voluntary process (unless made mandatory by a jurisdictional regulator or via a funding agreement) and, regulation by the TGA is not voluntary. Products must comply with medical device regulations (legal rules) unless they meet all the exclusion criteria (as set out on page 4 of this guidance).

The table below summarises the key high-level differences between the two frameworks:

	Framework arrangement	Oversight focus
TGA	mandatory	product
Commission	mix of voluntary and mandatory*	service provision

* Although oversight by the Commission is in many cases voluntary, there are some instances where it may become mandatory. For example, where a regulator like a state or territory health department directs a funded services to undergo accreditation to the NSQDMH, or, where a funding agreement for a non-government digital mental health service is required to undergo accreditation to access public funding.

When digital technology is a medical device

The Medical Device Regulations for software are technology agnostic. This means that the product can be any kind of technology such as a chatbot, mobile app, web app, server-based system, traditional desktop package, cloud-based, or any combination of these. It can also be a combination of software and/or hardware.

Many service providers who have digital mental health products deliver their service via apps, a website or other cloud-based architecture; this would not affect its regulatory status. What determines whether the product is regulated by the TGA is what it does and how it does it – as described in the “intended purpose” for the software.

Definition of 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

TGA regulation of digital mental health products

Following consultation with stakeholders, including with global medical device regulators, in 2019 and 2020, the Government amended the Medical Device Regulations to clarify existing requirements and to introduce some new requirements for software-based medical devices.

The changes took effect from 25 February 2021 and incorporated an exclusion for digital mental health products by amending the *Therapeutic Goods (Excluded Goods) Determination 2018*. Although many digital mental health products would be considered medical devices, this Determination 'carved-out' (excluded) some products from TGA regulation.

Exclusion of digital mental health products from TGA regulation

This exclusion is conditional and only acceptable if there is use of clinical practice guidelines in the digital mental health product. This requirement is specified in Schedule 1, item 14E of the Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021 as follows:

> "software that is a digital mental health tool (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software in a manner that is reviewable by the user"

- This means using established clinical practice guidelines in the design and
- Providing references to these guidelines within the product and
- Displaying these guidelines in the product so that the user can see them.

If a digital mental health product meets all of these conditions, it is excluded and therefore is not regulated as a medical device by the TGA, even if it diagnoses, monitors or treats a mental health illness or condition.

If a mental health product meets the exclusion conditions, the manufacturer/software developer/supplier does not need to make an application to the TGA or submit any other notification to the TGA. If a new additional feature or change is made to the mental health product, you should check if the change results in it no longer meeting the exclusion criteria and therefore requires an application to be submitted to the TGA and regulated as a medical device.

What is an established clinical practice guideline?

To be considered as established, a 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 accredited hospitals, colleges or societies have published the clinical practice guideline for use in patient care.

An example is Anxiety disorders: clinical practice guidelines and associated resources, which is published by the Royal Australian and New Zealand College of Psychiatrists.

Novel treatments that are supported by one or a small number of published scientific papers would not be considered an established clinical practice guideline. It must be recognised by a relevant health professional body or a national body such as the Commission.

What is regulated by the TGA?

If your software meets the definition of a medical device and fails to meet all of the conditions for the exclusion, it is regulated by the TGA and must be included in the Australian Register of Therapeutic Goods (ARTG). (see page 12 for where to find information on how to apply for inclusion of a medical device in the ARTG).

For example:

An app that monitors and determines treatment for severe depression, providing real-time alerts to clinicians for deterioration and suicide risk. A dashboard is provided to the health service provider for all their patients.

> When would a digital mental health product be regulated as a medical device?
>
> It would be regulated by the TGA if the digital mental health product was diagnosing,
> treating or monitoring a mental health illness or condition
> AND
> was not using a clinical practice guideline in the manner described above.

What is not regulated by the TGA?

Software that is used simply for display of guidelines, information sources/resources, registration, viewing, recording of results and tracking, facilitating telehealth consultations or for generation or update of a digital health record, is not medical devices and is not regulated by the TGA.

Similarly, software that solely:

- replicates published clinical practice guidelines and checklists, without any diagnostic, monitoring or treatment features
- enables uploading of results to a database for the purpose of facilitating further action

is not a medical device and is not regulated by the TGA.

For example:

An app that provides cognitive behavioural therapy (CBT) for mild anxiety, suggesting exercise and lifestyle changes to manage symptoms. The app does not diagnose anxiety– the consumer self-selects the app.

Software that has multiple functions and combines regulated and non-regulated features are regulated by TGA, and you will need to apply for inclusion in the ARTG for these products.

The assessment of such a product would predominantly focus on the medical device features but would also look at evidence showing that the performance of the regulated features is not impacted by the other, non-regulated features, and that any shared data stores or other components are validated accordingly. The assessment would also review the interaction between each of the components.

Oversight of digital mental health services

The Commission has developed an accreditation model for providers of digital mental health services to be assessed against the NSQDMH Standards.

Example Scenarios of Regulation

Some example scenarios are listed below to illustrate when a digital mental product is subject to medical device regulation by the TGA.

Example 1: Excluded from TGA regulation

A cognitive behavioural therapy (CBT) app that helps users manage severe anxiety. It references RANZCP's clinical practice guidelines at the start of the app and provides a link to the website.

Medical device regulatory status: Excluded – not regulated by the TGA.
Reason: The app references clinical practice guidelines, and provides a link to them, and the guidelines are widely accepted for use in Australia.
Eligible to seek NSQDMH Standards accreditation: Yes
Note: this is not a TGA requirement

Example 2: TGA regulated medical device

A web-based tool that consumers log into and enter a range of symptoms. The tool provides a customised profile including a diagnosis for depression and some suggested treatment options including CBT. The consumer is invited to regularly provide symptom updates; the tool provides charts and adjusts the treatment based on the progress observed.

The tool does not disclose the basis for the treatment, though it references a standard for depression diagnosis.

Medical device regulatory status: Regulated as a medical device and requires inclusion in the ARTG.
Reason: The tool diagnoses depression and suggest treatment, so it is a medical device. It is not excluded since it does not show that the algorithm is based on a clinical practice guideline.
Eligible to seek NSQDMH Standards accreditation: Yes
Note: this is not a TGA requirement

Example 3: TGA regulated medical device

A product for health care providers who can prescribe the app for their patients, when they have already been diagnosed with a specific condition, in this case severe depression. The app works with a cloud-based database and rules engine. The app enables patients to enter their daily symptoms and provides a daily monitoring dashboard to the health professional. The app provides a real time urgent alert to the healthcare professionals pager/phone/practice if the patient deteriorates rapidly or is deemed to be at risk.

The algorithm for the alerts and monitoring is not disclosed.

Medical device regulatory status: Regulated as a medical device and requires inclusion in the ARTG.
Reason: The product monitors the patients in real time, so it is a medical device. It is not excluded since it does not show that the algorithm is based on an established clinical practice guideline.
Eligible to seek NSQDMH Standards accreditation: Yes
Note: this is not a TGA requirement

Example 4: Excluded from TGA regulation

A website provides a range of quizzes and interactive games to help a user decide if they may be at risk of depression. A high-medium-low risk assessment is provided at the end of each quiz. Personal identifying information is not collected. The guidelines for depression are displayed prominently on the website. A range of resources are provided to the user depending on their responses including phone numbers and websites with mental health information.

Medical device regulatory status: Excluded – not regulated by the TGA.
Reason: The website is not a medical device because it does not diagnose – it provides only a simple High-Medium-Low indication. The website meets the conditions of exclusion because it prominently displays the guidelines for depression.
Eligible to seek NSQDMH Standards accreditation: Yes
Note: this is not a TGA requirement

Example 5: TGA regulated medical device

An app that monitors self-reported symptoms of anxiety, and monitors pulse rate that is collected by a smartwatch and sent to the app. The app diagnoses mental health conditions, displaying RANZCP guidelines and also diagnoses cardiac disease.

Medical device regulatory status: This app combines multiple features – while the mental help part of the app is excluded (not regulated), the other diagnostic feature for cardiac disease is regulated as a medical device. This means the app needs to comply with medical device regulations and the provider (the sponsor or manufacturer) must apply for inclusion on the ARTG prior to supplying the app.
Reason: The app diagnoses cardiac disease so the product is a medical device.
Eligible to seek NSQDMH Standards accreditation: Yes
Note: this is not a TGA requirement

Example 6: Excluded from TGA regulation

A patient mental health service that is delivered via a mobile app for inpatients in a particular health facility. The app monitors a range of self-reported mental health indicators of patients through their journey for this episode of healthcare which may include surgery, chronic disease or emergency treatment.

The app includes a symptom checker that is based on the facility's clinical practice guidelines. Results from the app are sent to the supervising clinician and following deidentification and consent, are sent to a partnering university for use in research. The clinical team may take action depending on the results from the app.

Medical device regulatory status: Excluded – not regulated by the TGA.
Reason: While the app includes a diagnostic and monitoring function which makes it a medical device, it uses and displays the healthcare facility's published clinical practice guidelines so meets the criteria for exclusion as a digital mental health tool.
Eligible to seek NSQDMH Standards accreditation: Yes
Note: this is not a TGA requirement

Privacy and data protection

Regardless of whether or not a product is regulated as a medical device, all other Australian privacy and data protection laws would still apply (e.g. *Privacy Act 1988*).

Post-market monitoring and standard conditions of inclusion in the ARTG

All suppliers (sponsors) of software included in the ARTG have ongoing responsibilities under the *Therapeutic Goods Act 1989*, the Therapeutic Goods (Medical Devices) Regulations 2002, and the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021, including conditions that apply automatically to all ARTG entries as described in Post market responsibilities for manufacturers and sponsors of medical devices. These conditions facilitate post-market monitoring and include, but are not limited to, the following:

- allowing entry and inspections of premises
- delivery of device samples upon request
- availability of information, such as facilitating access to technical documentation that demonstrates compliance with the essential principles
- ensuring any advertising material relating to the medical device complies with regulatory requirements
- reporting details of certain incidents and performance issues to the TGA, and any overseas regulatory actions to the TGA if the product involved is from the same batch or production run that was supplied in Australia.

All sponsors are also required to report adverse events to the TGA.

Post-market reviews

The TGA can conduct a post-market review of certain kinds of devices included in the ARTG. ARTG entries for software may also be subject to a post-market review. If a post-market review occurs, the TGA will formally write to all affected sponsors of devices subject to the review.

How to apply to the TGA for ARTG inclusion of your mental health product

- Check all of the requirements in this document.
- As a potential sponsor, you will need to establish a client identification number (Client ID) to access the secure online TGA Business Services (TBS)
- You will then need to submit and have your manufacturer's evidence (conformity assessment certification) accepted by the TGA prior to being able to submit your application for inclusion
- Once your manufacturer's evidence is accepted you will be able to submit an application for your software product to be included in the ARTG
- Ensure that you are complying with Australian privacy and data protection laws
- If you need further information and detailed guidance on the regulation of software based medical devices, see Regulation of software based medical devices.

Advertising requirements

Advertisements in the public domain for medical devices are subject to the requirements of the Act, including the requirement to comply with the Advertising Code.

The Advertising Code specifies the requirements for advertising therapeutic goods to consumers. Notably, it requires that advertising for therapeutic goods must:

- be accurate, balanced, and not misleading or likely to be misleading and that all information presented has been substantiated
- be consistent with the intended purpose on the ARTG
- present the good in accordance with the directions/instructions for use.

Additionally, advertisements for therapeutic goods must **not:**

- contain any claim, statement, implication or representation that the goods are safe, their use cannot cause harm, that they have no side effects or that the goods are effective in all cases
- exaggerate the efficacy or performance of the product or encourage inappropriate use
- state or imply that the goods are approved or endorsed by a government authority (e.g. stating "TGA approved")
- must not be likely to lead people to delay necessary medical attention
- must not be inconsistent with public health campaigns.

> It is also important to be aware that representations in consumer advertising that refer to the detection of COVID-19, are "restricted representations". Under the Act, restricted representations must not be used in consumer advertising without prior approval or permission from the TGA. Notices of approved and permitted representations are published on the TGA website.
>
> The TGA has published two fact sheets for sponsors and manufacturers of software – one about advertising to consumers and one about advertising to health professionals.
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> More information on complying with the Advertising Code is available at Complying with advertising requirements and further general information on advertising is available via the advertising topic page.
>
> Enquiries about the legislative requirements for advertising therapeutic goods can be lodged online at Make an advertising enquiry.

Contact the TGA or the Commission

If you have questions or would like to have a discussion with the TGA, please contact us at:

Digital.Devices@tga.gov.au

General medical device enquiries:
devices@tga.gov.au
1800 141 144

Australian Commission on Safety and Quality in Health Care Advice Centre:
AdviceCentre@safetyandquality.gov.au
1800 304 056

Topics: Advertising

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