



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Consultation:

Reviewing the exclusion for certain digital mental health tools

October 2026

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Introduction

The Therapeutic Goods Administration (TGA) regulates therapeutic goods, including medical devices, to help protect and improve the health of Australians. 'Medical devices' can include software products like digital mental health tools (DMHTs).

DMHTs can play an important role in improving access to mental health support. Governments, health services and private organisations increasingly use these tools to support consumers and health professionals.

Although the TGA usually regulates these tools, in 2021 a subset of DMHTs were removed (excluded) from regulation. This exception is known as the DMHT exclusion and is based on specific criteria. The exclusion was introduced to avoid duplicating requirements expected to be included in the new National Safety and Quality Digital Mental Health Standards. DMHTs were not commonly used at that time, and those meeting the exclusion criteria were considered to be very low risk.

In 2024, we reviewed the regulation of medical software and artificial intelligence (AI) in Australia.¹ The review found that the DMHT exclusion may no longer be appropriate, given the increasing complexity and risk profiles of these products. In addition, the National Digital Mental Health Standards are only applicable to service providers, and don't cover product-specific requirements. As a result, we are reviewing the suitability of the DMHT exclusion and are now seeking feedback on whether it should be kept, removed, or modified.

Digital mental health tools (DMHTs)

DMHTs are software products, like apps and websites, that offer assessment, therapy, or self-management strategies to support mental health care. They can be used for many conditions, such as depression, anxiety, eating disorders, addiction, post-traumatic stress disorder and sleep-related conditions. They can be recommended by health professionals or accessed directly by consumers without any health professional oversight.

Examples include:

- Apps that provide cognitive behavioural therapy to help manage anxiety symptoms
- Online platforms that use questionnaires to screen for depression and recommend next steps based on the result
- Chatbots providing personalised intervention to people experiencing mental health challenges

How DMHTs are currently regulated

A DMHT meets the TGA's definition of a medical device if it is intended by its manufacturer (developer) to *screen for, diagnose, prevent, monitor, predict, treat or support the management of* a mental health condition (*Therapeutic Goods Act 1989*).²

We regulate DMHTs when they:

- meet the definition of a medical device, and
- do not meet any relevant exclusion criteria.

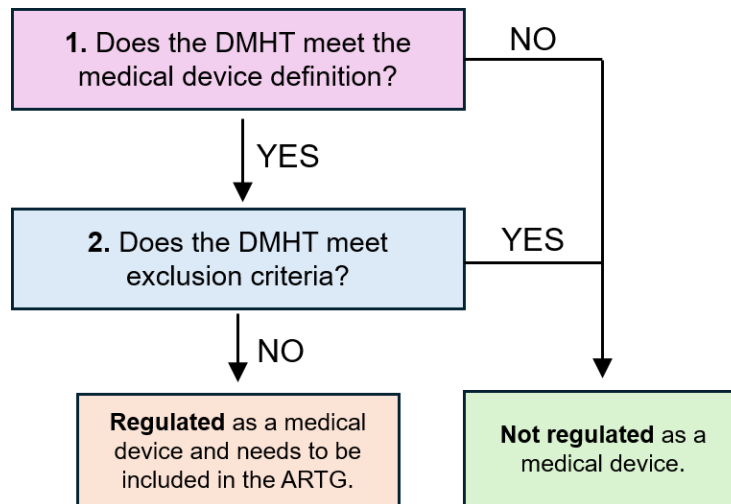
Figure 1 illustrates when a DMHT is regulated.

¹ Finding 8 in *Clarifying and strengthening the regulation of medical device software including artificial intelligence (AI)*; available at: [tga-report-clarifying-and-strengthening-the-regulation-of-medical-device-software-including-artificial-intelligence-aipdf](#)

² Section 41BD of the [Therapeutic Goods Act 1989](#)

To legally supply a DMHT intended for such uses in Australia (or to import/export it), the DMHT must be included in the Australian Register of Therapeutic Goods (ARTG). ARTG inclusion involves the product sponsor demonstrating they meet specific requirements. These apply both before a product is supplied and while it remains on the market. The requirements are proportionate to the level of risk associated with the product. For more information, see [Understanding how we regulate software-based medical devices](#).³

Figure 1. Decision tree showing when a DMHT is regulated by the TGA.



When is software (including DMHT) a medical device?

Software is a medical device when the manufacturer intends for their product to be used for:

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



Who has regulatory responsibilities to the TGA?

- **Manufacturers (developers):** The person or company legally responsible for making the software. This is often the software developer.
- **Sponsors (suppliers/developers/providers):** The person or company responsible for supplying the software in Australia or exporting it.

Both these parties have legal obligations under our framework.

The DMHT exclusion⁴

In 2021, following public consultation, a subset of DMHTs were excluded from regulation based on meeting specific criteria.

³ Understanding how we regulate software-based medical devices; available at:

<https://www.tga.gov.au/resources/guidance/understanding-how-we-regulate-software-based-medical-devices>

⁴ Item 14E, Schedule 1 of the [Therapeutic Goods \(Excluded Goods\) Determination 2018](#)

The [DMHT exclusion](#)⁵ applies to:

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.*

An example is a website that offers self-guided behavioural therapy to help treat anxiety. These therapy sessions would need to follow current clinical practice guidelines published by the Royal Australian and New Zealand College of Psychiatrists, with the website linking directly to these guidelines. This supports transparency by allowing users to review the evidence base for the tool's outputs.

Excluded products are not regulated by the TGA, but these products are still subject to other non-TGA regulations, like Australian Consumer Law, advertising and data privacy laws.

The DMHT exclusion is one of several software exclusions in place. Although some of these exclusions may also apply to DMHTs, they are not the focus of this consultation (see [Appendix A](#) for other software exclusions that may also apply to DMHTs).

Overseas regulation of DMHTs

International alignment of regulations can increase patients' access to products in Australia, and improve regulatory efficiency for products supplied in multiple markets. Most comparable overseas regulators consider DMHTs as medical devices when they meet that definition. The TGA's DMHT exclusion is out of step with comparable regulators. The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has excluded some DMHTs if they have only low functionality considered to pose a very low risk (such as storing data or showing fixed content). The United States Food and Drug Administration (US FDA) also does not actively regulate some DMHTs considered to be low risk or for general wellness use only.

A summary of overseas DMHT regulation is provided in [Appendix B](#).

Accreditation of digital mental health service providers

The Australian Commission on Safety and Quality in Health Care has published National Safety and Quality Digital Mental Health Standards. These guide service providers in the delivery of safe and high-quality digital mental health care services, through voluntary accreditation. The standards apply to *service providers*, not individual tools or products. The TGA is therefore the only body that regulates the safety, quality and performance of DMHTs when they are medical devices.

Review of the DMHT exclusion

In 2024, the TGA's review of the regulation of medical software and AI found that the DMHT exclusion should be examined to see if it is still fit for purpose. This is because software is evolving rapidly, so that even higher-risk products might be unintentionally excluded from regulation, with no one reviewing the product to ensure safety and performance for users.

During 2025–26, we carried out a review of the DMHT exclusion by engaging with key stakeholders to better understand the use of DMHTs in Australia, clarify any concerns with the current exclusion, and to inform potential regulatory options. This work has included:

⁵ Understanding the digital mental health tool software conditional exclusion, available at: <https://www.tga.gov.au/resources/guidance/understanding-digital-mental-health-tool-software-conditional-exclusion>

- Surveys of DMHT users ([response summary](#))⁶, software developers and providers
- Market research on consumer-facing health software
- Workshops with our DMHT expert group, comprising more than 20 experts from the mental health sector, academia, and government
- Meetings with the [Technical Reference Group on Software as a Medical Device and AI](#)⁷
- Discussions with other parts of the Department of Health, Disability and Ageing, including the Australian Commission on Safety and Quality in Health Care and the National Mental Health Commission
- Discussions and research about the approaches taken by comparable overseas regulators.

The feedback received, together with other information gathered during the review, has informed the problem statement and the options presented in this paper.

The problem with the exclusion

Since the introduction of the exclusion for some DMHTs in 2021, these tools have proliferated and become more diverse and complex, including many which now use AI. DMHTs have been developed for many conditions, such as depression, anxiety, addiction, bipolar disorder and attention deficit hyperactivity disorder. Many tools are marketed directly to consumers, who often select and use these tools without health professionals being involved.

Our research also found that consumers generally expect products to have been independently checked to ensure they are safe and effective. But excluded products are not subject to the TGA's oversight, so this expectation isn't being met.

DMHTs can provide many benefits. However, they can also cause harm. For example, they may give a person the wrong assessment, provide unsuitable advice, miss signs that urgent help is needed, or delay someone getting the care or treatment they need. Normally, TGA regulation sets minimum requirements for safety and performance to protect users from harm. But these requirements don't apply to excluded products.

The DMHT exclusion is based on three criteria which together show that a product may pose a low-enough risk to not need TGA oversight:

- the DMHT must be based on established clinical practice guidelines,
- which must be referenced and displayed in the software,
- in a manner that is reviewable by the user.

However, these criteria do not account for a product's intended purpose, user groups, output types, clinical claims or the consequences if it doesn't work as intended. As a result, products with higher-risk characteristics might qualify for the exclusion or be supplied, creating a gap in regulatory oversight and user protection. DMHTs can be used for purposes where inaccurate outputs could be harmful, like assessing and monitoring mental health conditions. These tools are also becoming more sophisticated in their functionality and may incorporate personalised recommendations or AI. These aspects can introduce extra risks, depending on how the technology is used.

Established clinical practice guidelines provide an important evidence base for mental health care. However, they vary in quality and detail and regularly become out of date. They are also

⁶ Digital Mental Health Tools User Survey, available at: <https://consultations.tga.gov.au/tga/digital-mental-health-tools-user-survey/>

⁷ Technical Reference Group on Software as a Medical Device and AI; available at: <https://www.tga.gov.au/about-us/committees-and-advisory-bodies/technical-reference-group-software-medical-device-samd-and-artificial-intelligence-ai>

written for health professionals, so although users can review the information, it may not help consumers easily judge if a DMHT is safe and up to date. Finally, being based on a clinical practice guideline doesn't ensure that the product works properly and is safe for the people it's intended to help.

Sponsors supplying excluded products are not required to collect and evaluate complaints, investigate safety concerns or report adverse events (side effects) to the TGA. This limits the ability to detect real-world risks as they emerge, creating a safety gap.

Overall, the exclusion may no longer be proportionate to the range and risk profile of DMHTs available now and in the future. It's possible that the current exclusion criteria might compromise user safety by removing products from TGA oversight and the requirements for safety, performance and quality this oversight provides.

Options for regulatory change

Option 1: No change to the DMHT exclusion (status quo)

Under this option, DMHTs meeting the existing exclusion criteria remain excluded from TGA regulation. No changes to their regulation would be made.

Benefits and risks of Option 1

One benefit of this option is that sponsors and manufacturers of DMHTs that meet the exclusion criteria will have no new regulatory obligations. Access to these DMHTs is therefore unlikely to be impacted.

However, this option does not address the reported issues with the exclusion. Products with potentially higher risk profiles may continue to fall outside regulatory oversight. Some stakeholders have raised concerns that continuing to exclude certain DMHTs may not protect users enough from harm.

This option would not meet public expectation that available products have some independent regulatory oversight. Australia's regulatory approach would also remain out of step with overseas approaches to DMHTs.

Option 1 Consultation questions	
Question 1	Do you support retaining the current DMHT exclusion without change? [Yes/No/Maybe] Please explain your answer, considering the potential benefits and risks of this option (for example, impacts on user safety, access, innovation, regulatory burden).
Question 2	Does the current exclusion appropriately determine which DMHTs do not require TGA oversight? [Yes/No/Maybe] Please explain your answer.
Question 3	What, if any, unintended consequences do you foresee with this option?

Option 2: Removing the exclusion

Under this option, the DMHT exclusion would be removed from the regulatory framework. Products that currently meet the DMHT exclusion criteria would generally become regulated medical devices when they meet that definition. Sponsors and manufacturers would need to meet regulatory requirements, such as ARTG inclusion and collecting and reporting adverse events, to keep supplying these products.

ARTG inclusion applies risk-proportionate oversight to DMHTs, with obligations based on the classification of the medical device. More information about ARTG inclusion requirements, device classification and associated fees is provided in [Appendix C](#).

Benefits and risks of Option 2

Potential benefits include:

- Greater safety oversight, with DMHTs required to meet TGA requirements for safety, quality and performance
- Risk-based regulation, with higher-risk products subject to greater oversight than low-risk products
- Greater transparency, with information publicly available in the ARTG, and adverse events getting published
- Meeting consumer expectations
- Better understanding of emerging risks to users, through collection, assessment and reporting of complaints and adverse events
- Greater alignment with overseas regulatory approaches
- Simpler software regulation and better stakeholder understanding

On the other hand, this option would impose obligations for DMHTs that are currently excluded, which brings administrative and [cost](#)⁸ burden. Sponsors might also experience design and development difficulties with ensuring their product meets the TGA's rules. This could lead to some DMHTs being removed from supply by their sponsors, which might negatively impact users already relying on these tools.

Not having this exclusion available could also risk some sponsors choosing not to bring a product to market, due to the cost and potential difficulties associated with regulatory compliance. These impacts could be managed through appropriate transition arrangements, targeted stakeholder education, and clear guidance (see [Transition arrangements to support stakeholders](#)).

Option 2 Consultation questions	
Question 4	Do you support removing the DMHT exclusion? [Yes/No/Maybe] • Please explain your answer, considering the potential benefits and risks of this option (for example, impacts on user safety, access, innovation, regulatory burden).
Question 5	What would be the likely practical impacts of removing the exclusion?
Question 6	<i>For sponsors of DMHTs meeting the current exclusion criteria:</i> What is your expected regulatory burden or cost impact associated with this option?

⁸ Summary of fees and charges to applications submitted to the TGA, available at: <https://www.tga.gov.au/products/regulations-all-products/fees-and-payments/summary-fees-and-charges/summary-fees-and-charges-applications-submitted-tga>

	If this option were implemented, would you expect to stop supplying your product? [Yes/No/Maybe]
Question 7	What, if any, unintended consequences do you foresee with this option?

Option 3: Modifying the exclusion criteria

The objective of this option would be to keep an exclusion for very low-risk DMHTs, while bringing higher-risk products within regulatory oversight. The 'established clinical practice guidelines' criteria could be replaced by other factors, such as focusing on intended purpose or functionality. This could better clarify which DMHTs should not be regulated.

Other regulators provide example approaches ([Appendix B](#)). The UK MHRA does not regulate 'low-functionality' DMHTs.⁹ Low functionality means very simple computational tasks, like storing or communicating data with no change or prioritisation (i.e. replacing pen and paper). An example is a digital diary that records depression symptoms and displays them graphically without interpretation.

The US FDA has focused on carving out 'general wellness' products.¹⁰ An example of a DMHT in this category is software that provides daily motivational tips to reduce stress and promote a positive mental outlook. The TGA has similar exclusions in place already ([Appendix A](#)), but there may be scope to improve clarity for DMHTs specifically.

Under this option, we could change the exclusion criteria to clarify when a DMHT is not regulated as medical device. As with Option 2, this would mean products that meet the current DMHT exclusion criteria would generally become regulated medical devices, unless they are low-risk enough to stay excluded under any new criteria.

Benefits and risks of Option 3

The potential benefits of this option are similar to Option 2, centred on improving risk-based regulation of DMHTs, greater safety, and improved alignment to consumer expectations. Depending on the specific approach taken, it might align DMHT regulation more closely with overseas jurisdictions, which brings regulatory simplicity and efficiency.

The main challenge is developing criteria that are risk-based and sufficiently clear to distinguish low-risk products from those needing regulation. Any new criteria would also need to be adaptable enough for future changes in technology. Different interpretations of the criteria could create ongoing uncertainty for sponsors.

As with Option 2, this option would impose obligations for DMHTs that are excluded based on the existing criteria, which could impact access to some of these tools. It may also prompt some sponsors to avoid bringing their product to market, due to cost, administrative efforts, and product design impacts. Again, such an impact could be mitigated through transition arrangements and stakeholder education.

Option 3 Consultation questions	
Question 8	Do you support changing the DMHT exclusion criteria? [Yes/No/Maybe]

⁹ Digital Mental Health Technology - Regulation and Evaluation for Safe and Effective Products, available at: <https://www.gov.uk/government/publications/digital-mental-health-technology-qualification-and-classification>

¹⁰ General Wellness: Policy for Low Risk Devices; available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>

	Please explain your answer, considering the potential benefits and risks of this option (for example, impacts on user safety, access, innovation, regulatory burden).
Question 9	What characteristics should be considered when determining whether a DMHT is low-risk enough to remain excluded from regulation? For example: - intended purpose - functionality - target user group - clinical claims - use of AI or personalised recommendations - deterioration identification and escalation to appropriate care - how likely the tool is to be used by people for whom it isn't intended
Question 10	What would be the likely practical impacts of this option?
Question 11	What, if any, unintended consequences do you foresee with this option?

Transition arrangements to support stakeholders

If Option 2 or 3 is taken forward, a transition period could be offered to sponsors of DMHTs that meet the current exclusion criteria, as they would become subject to new requirements. Transition periods are intended to provide sponsors with enough time to understand the new rules, update processes, obtain certification if needed, and integrate regulatory obligations into their workflows. During a transition period, the new rules do not yet apply (if certain conditions are met).

We propose a 2-year transition period. During this time, sponsors would need to take steps to comply with the new requirements and apply for ARTG inclusion.

We also propose sponsors should be required to notify the TGA of their intention to transition a DMHT that is already in supply. Such a notification would provide visibility to the TGA, supporting improved stakeholder communication, implementation planning, and compliance.

Once the transition period is over, any DMHT that is subject to the new rules would need to comply with those rules or no longer be supplied in Australia.

Transition arrangements – consultation questions	
Question 12	If Option 2 or 3 is implemented, would a 2-year transition period for affected DMHTs be appropriate? [Yes/No/Maybe] Please explain your answer.
Question 13	If a transition period were offered, should sponsors be required to notify the TGA in order to access the transition period? [Yes/No/Maybe] Please explain your answer.

What we invite you to do

Please consider and respond to the questions in this consultation paper. You can provide your feedback at <https://consultations.tga.gov.au/tga/consultation-dmht-exclusion>.

Following internal review of feedback received, the consultation outcomes will be published on the TGA website. This is expected to occur in early 2027.

Please direct questions to EmergingTechnology@health.gov.au.



This consultation closes at 23:59pm AEDT on 7 Dec 2026

Next steps

We will use the consultation responses to identify a suitable regulatory option and recommend it to the Government.

Appendix A: Exclusions that may apply to DMHTs¹¹

Exclusion	Criteria	Example
Behavioural change and coaching	a. intended by its manufacturer to be used by a consumer to improve general health or wellness by coaching, or encouraging behavioural change, in relation to personal or environmental factors, such as weight, exercise, sun exposure or dietary intake; and b. not intended by its manufacturer to be used: – in clinical practice or to provide information to the consumer that would generally be accepted to require the interpretation of a health professional; or – for the purpose of diagnosis, prognosis, or making a decision about the treatment, of a disease, condition, ailment or defect.	An app for learning mindfulness meditation that includes daily reminders to complete a meditation exercise to improve general wellness.
Patient surveys	a. intended by its manufacturer to be used as a patient reported outcome measures (PROMs) questionnaire or patient survey; and b. not intended by its manufacturer to diagnose, screen for, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment, or defect.	A webpage that digitises a survey used to assess the severity of depression and emails the results to a health professional without interpretation or making recommendations.
General health and wellness	a. intended by its manufacturer to be used by a consumer to promote or facilitate general health or wellness by measuring or monitoring (through non-invasive means) a physical parameter, such as movement, sleep, heart rate, heart rhythm, temperature, blood pressure or oxygen saturation; and b. not intended by its manufacturer to be used: i. in clinical practice; or ii. treatment, or making a recommendation or decision about the treatment, of a serious disease or a serious condition, ailment or defect.	A mobile phone app that monitors the user's heart rate, tracks stress levels and provides relaxation exercises to improve general wellbeing.
Health self-management	a. intended by its manufacturer to be used by a consumer for the self-management of an existing disease, condition, ailment, or defect that is not a serious disease or serious condition, ailment, or defect; and b. not intended by its manufacturer to be used: i. in clinical practice; or ii. in relation to a serious disease or serious condition, ailment, or defect; or iii. for the purpose of diagnosis, treatment, or making a specific recommendation or decision about the treatment, of a disease, condition, ailment, or defect that is not a serious disease or serious condition, ailment, or defect.	An app that helps a user self-manage mild stress through breathing exercises, mindfulness activities and wellbeing tracking, without providing diagnosis, treatment recommendations or clinical assessment.

¹¹ Software-based medical device exclusions; available at: <https://www.tga.gov.au/products/medical-devices/software-and-artificial-intelligence-ai/overview/software-based-medical-device-exclusions>

Appendix B: Overseas regulation of DMHTs

Regulator	Regulation of DMHTs (accurate as of 9 Sep 2026)
United States Food and Drug Administration ^{12,13}	- Regulates software that meet the definition of a medical device - Exercise enforcement discretion for software functions that meet the definition of 'medical device' and pose lower risk to the public - Excludes general wellness products; e.g. tools to encourage healthy eating, exercise, weight loss
Medicines and Healthcare products Regulatory Agency (UK) ^{14,15}	- Regulates software that meet the definition of a medical device - Regulates software with medical purpose and high functionality - e.g. DMHT that uses complex algorithms/AI to summarise patient information and report probabilities of mental health conditions - Excludes software with 'low functionality' - e.g. software that only stores or communicates data with no change
European Union Medical Device Regulation ¹⁶	- Regulates software that meets the definition of a medical device - Excludes general wellbeing apps that lack a medical purpose, or if used for simple storage, archiving, or communication
Health Canada ^{17,18}	- Regulates software that meet the definition of a medical device - Excludes general wellness applications, healthcare administration tools, and electronic health record systems - Mental health apps can be assessed by the Mental Health Commission of Canada and receive a badge if they meet required standards
Health Sciences Authority (Singapore) ¹⁹	Regulates software that meet the definition of a medical device
Pharmaceuticals and Medical Devices Agency (Japan) ²⁰	- Regulates software that meet the definition of a medical device - Excludes the regulation of software with limited potential to impact patient health if it malfunctions such as patient education software
Ministry of Food and Drug Safety (Korea) ²¹	Regulates digital health technologies under the Digital Medical Products Act (DMPA), which may also capture general wellness products

¹² Policy for Device Software Functions and Mobile Medical Applications; available at: <https://www.fda.gov/media/80958/download>

¹³ Examples of software functions for which the FDA will exercise enforcement discretion; available at: <https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-which-fda-will-exercise-enforcement-discretion>

¹⁴ Digital Mental Health Technology - Regulation and Evaluation for Safe and Effective Products, available at: <https://www.gov.uk/government/publications/digital-mental-health-technology-qualification-and-classification>

¹⁵ Medical devices: software applications; available at: <https://www.gov.uk/government/publications/medical-devices-software-applications-apps>

¹⁶ MDCG 2019-11 Rev.1 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR; available at: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

¹⁷ Guidance Document: Software as a Medical Device (SaMD): Definition and Classification; available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html>

¹⁸ Assessment Framework for Mental Health Apps; available at: <https://mentalhealthcommission.ca/app-assessment/>

¹⁹ Health Products (Medical Devices) Regulations 2010; available at: <https://sso.agc.gov.sg/SL/HPA2007-S436-2010?ProvlDs=P11->

²⁰ Software as a Medical Device (SaMD); available at: <https://www.pmda.go.jp/english/review-services/reviews/0009.html>

²¹ Digital Medical Products Act, available at: https://elaw.klri.re.kr/eng_mobile/viewer.do?hseq=69456&type=part&key=36

Appendix C: Device classification and obligations for regulated DMHTs

DMHTs that meet the definition of a medical device must be included in the Australian Register of Therapeutic Goods (ARTG), unless they are subject to an exclusion or exemption.

The regulatory requirements and TGA oversight that apply to a DMHT is scaled according to the device classification. Higher-risk devices are subject to greater regulatory oversight than lower-risk devices.

Device classification is based on different factors that help determine the level of risk posed by the DMHT, for example:

- Intended purpose
- The seriousness of the conditions the software is intended for
- Risk to public health
- User type (consumer or health professional)

Table 1 gives examples of regulated DMHTs and their likely device classification under the framework. Detailed guidance can be found at [Classifying active medical devices in Australia \(including software-based medical devices\)](#).

Table 1: Examples of DMHTs and their likely device classification.

DMHT example	Device classification
Webpage offering self-guided cognitive behavioural therapy to help manage mild symptoms of depression	Class I
- App that provides cognitive behavioural therapy for bipolar disorder - Online platform that uses questionnaires to screen for depression and recommends next steps based on the result - Generative AI chatbot providing personalised intervention to people experiencing mental health challenges	Class IIa Class IIb
App that screens for acute psychosis and provides a diagnosis directly to the user	Class III

ARTG inclusion obligations

For regulated DMHTs, the ARTG inclusion pathway generally involves four stages:

1. Meet safety, performance, and design requirements

- Meet standards to ensure software is safe and performs as intended (known as the Essential Principles)
- Implement a formal quality management system (Class IIa and above)
- Establish a post-market surveillance system
- Maintain appropriate records and controls

2. Obtain certification (for Class IIa and above)

3. Apply for ARTG inclusion

- Submit application, and pay the [fees](#)²²
- Supply software once the application is approved

²² Summary of fees and charges to applications submitted to the TGA, available at: <https://www.tga.gov.au/products/regulations-all-products/fees-and-payments/summary-fees-and-charges/summary-fees-and-charges-applications-submitted-tga>

4. Meet ongoing obligations after supply

- Keep records
- Monitor software performance
- Report adverse events
- Comply with advertising rules
- Meet other post-market obligations such as market and recall action

Overall, the oversight applied is proportionate to the classification of the software, summarised in **Table 2**.

Table 2: Regulatory requirements according to the medical device classification.

Requirements	Class I	Class IIa and IIb	Class III
Meet standards for safety, quality and performance (Essential Principles)	✓	✓	✓
Meet manufacturing requirements	✓	✓	✓
Obtain quality management system certification	No	✓	✓
Obtain design certification	No	No	✓
Meet after-supply obligations	✓	✓	✓

For more information, see [Understanding how we regulate software-based medical devices](#).

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