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How is AI regulated for mental health in Australia?

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Australia has no AI-specific legislation for mental health. Australia is taking a whole-of-government approach to regulation using existing laws (e.g., online safety, therapeutic goods). While regulation is complex, companies can be held liable and the evidence-base for liability is increasing.

AI is regulated via:

- **Online Safety Act (2021):** Under the Act, the eSafety Commissioner oversees online safety codes and standards that apply to AI-generated content.
- **Therapeutic Goods Administration (TGA):** Regulates AI in medical device software.
- **Privacy act (1998):** The Privacy and Other Legislation Amendment Act 2024 included measures relevant to AI and personal data use.
- **Australian Consumer Law:** AI is regulated under existing consumer law protections, e.g., AI-generated claims/chatbot responses must not mislead consumers and products must be of acceptable quality.
- **Office of the Australian Information Commissioner (OAIC):** Australia's independent privacy regulator responsible for administering the Privacy Act 1988 - has published guidance on privacy and the use of commercially available AI products.

Upcoming reforms:

- **Digital Duty of Care:** Will require online services/platforms to take reasonable steps to prevent foreseeable online harms, including those associated with AI.
- **Automated Decision-Making:** From Dec 2026, organisations must disclose when personal information is used by automated systems to make, or significantly assist with, decisions affecting individuals' rights or interests.

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Australian mental health professionals using AI must comply with:

- TGA Regulation (where AI qualifies as a medical device)
- Privacy Act 1988
- AHPRA Professional Requirements
- ACSQHC Guidance
- Professional Standards, Guidelines & Policies

When is an AI technology considered a medical device?

An AI technology used in mental health could be considered a medical device if it is intended for the **diagnosis, prevention, monitoring, prediction or prognosis, treatment or alleviation** of a mental health condition.

What about AI used in digital mental health interventions*?

AI used in digital mental health interventions (e.g., apps) is regulated through the TGA's Software as a Medical Device (SaMD) framework*. An AI tool designed to diagnose depression or recommend treatment for anxiety would likely require TGA oversight.

Are general purpose AI chatbots (e.g., ChatGPT, Claude) regulated?

These technologies were **not** developed to diagnose, monitor or treat mental health conditions and consequently, typically fall outside TGA regulation. However, chatbots may be subject to Australian privacy and online safety laws, particularly where they collect, use, generate, store, or disclose personal information, or facilitate online interactions and content.

*Note, apps may be exempt if they automate established clinical processes without making new claims regarding diagnosis or treatment (e.g., screening tools with established clinical guidelines).

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Not all chatbots are the same ...

There are multiple different types of chatbots that can be used for different purposes. Examples of different types of chatbots used for mental health information and support are shown below.

TGA approved mental health chatbots	Chatbots that are backed by research and clinical trials to prove their safety and efficacy. There are currently (mid-2026) no AI mental health technologies (including chatbots) registered on the Australian Register of Therapeutic Goods (ARTG) to "diagnose, treat or cure mental health conditions".
Direct-to-consumer mental health chatbots	Chatbots that can be delivered, direct-to-consumers, outside of mental health settings. They are designed by clinicians, evidence-based and grounded in psychological science (e.g., Therabot (Heinz et al., 2025) and Woebot (Campellone et al., 2025). These are not well known or easily accessible by the public.
Direct-to-consumer general chatbots (e.g., ChatGPT, Claude, Gemini)	Unregulated chatbots that were designed for interactive conversation and entertainment and are easily accessible for free (or low cost) online. These chatbots are increasingly being used for mental health support, however they are not evidence-based and lack human oversight.

References:

- Campellone et al. (2025). Safety and User Experience of a Generative Artificial Intelligence Digital
- Heinz et al. (2025). Randomized Trial of a Generative AI Chatbot for Mental Health Treatment

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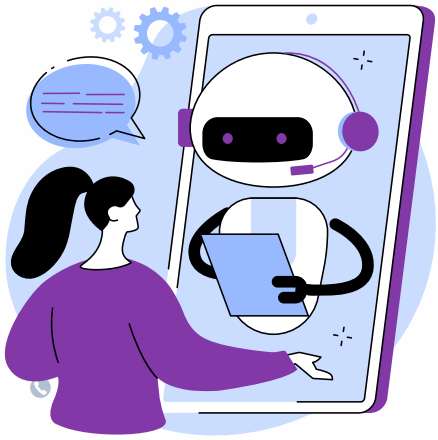
Many AI technologies being used to access mental health information and support were developed outside Australia but are readily accessible online. While international cooperation on AI safety continues, growing geopolitical competition has complicated efforts to establish a consistent global approach to AI governance.

What risks do unregulated AI technologies pose?

While privacy law, professional standards and medical device regulations provide some protections, they do not adequately address emerging risks associated with the use of AI (e.g., chatbots, AI scribes) for mental health purposes.



Risks include:

- Data sovereignty and privacy.
- Bias and discrimination.
- Mental health misinformation.
- Data storage on overseas servers.
- Chatbot sycophancy (chatbots can be highly agreeable, telling users what they want to hear).
- Limited accountability on developers.
- No mechanisms to monitor adverse events or mitigate risks.

Australia's regulatory environment for AI in mental health is evolving ... While AI tools that meet the definition of a medical device are subject to specific regulation, many consumer-facing tools are primarily governed by broader laws, including privacy and online safety requirements, rather than AI-specific regulation.

Further reading:

- Black Dog Institute (2026). AI in Mental Health Roundtable Report
- Maidment et al. (2026). Policy and regulation for AI in Mental Health in Australia

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