

Health service use of unregulated Artificial Intelligence (AI)

Health Service Advisory

FINAL OFFICIAL

Purpose

This Advisory is issued in response to emergence of new generative AI programs such as ChatGPT and similar generative AI models. It outlines the interim position on safe use; no such application is listed on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG).

This Advisory requires Victorian health services to:

- align any clinical use of 'generative artificial intelligence' (AI) software, such as ChatGPT, with national regulation, and
- establish local procedures to authorise the use of AI in health care, and ensure that its use satisfies regulatory obligations

This Advisory is intended for all clinical and technical staff in Victorian public health agencies.

Advisory - Clinical use of Generative AI

Unregulated generative AI software such as ChatGPT and other, similar, software should not be used for any clinical purpose. This includes:

- clinical applications of generative AI, such as the generation of discharge summaries
- clinical support functions that use generative AI, such as generation of summaries from patient notes and/or EMR records
- consumer support functions, such as conversational triage 'bots'
- integration of generative AI into clinical services, such as talk-to-text summaries and/or translations, post consultation.

Large language models (see **Appendix 1**) and generative AI are subject to TGA regulation if their use is for a medical purpose. TGA states that 'regulatory requirements are technology-agnostic for software-based medical devices. Software as a medical device regulation applies regardless of whether the product incorporates components like AI, chatbots, cloud, mobile application or other technologies'.

Obligations for 'Chat, Text and Language' artificial intelligence when its intended use is for medical (health) care described on the TGA website at:

[Regulation of software based medical devices | Therapeutic Goods Administration \(TGA\)](#)

There are a number of appropriate uses of AI driven tools to enhance business, analytic and administrative functions, and some medical AI has been certified by the TGA. Health services are required to apply clinical and executive assessment and sign off on uses of AI, as for local use of medical technology and devices. This includes the use of commercial generative AI programs that may be imbedded into other clinical applications, and software that is marketed as clerical or administrative support.

Context

The Therapeutic Goods Administration (TGA) is responsible for the regulation of Artificial Intelligence (AI) when it has a therapeutic (medical) intended purpose in health care in Australia. Artificial Intelligence software and models that have undergone assessment by the TGA are listed on the Australian Register of Therapeutic Goods (ARTG)¹.

Risks

The risks of generative AI are not unique to health. Many industries recognise the opportunity and are working towards a solution to ensure safe use. In summary, the known issues are generative AI are as follows:

Inaccuracies: Generative AI must be ‘trained’ on a dataset before it’s implemented. The outputs from AI are only as good as the information it has learnt, but these applications are unlikely to include training on specific clinical tasks. AI does not ‘understand’ this information; it identifies patterns and trends in data. Generative AI can create information that is incorrect or inaccurate – commonly called ‘hallucinations’ – with no content knowledge that can identify and correct these mistakes.

Source of bias: Training databases may include sources of bias – including under- or misrepresentation of minority groups. Generative AI will create outputs with these biases, sometimes labelling them as fact. This is particularly concerning when AI software is trained on international data without important corrections for local demographics.

Transparency: Generative AI is often labelled as a ‘black box’ technology. Most users are unaware of how the software ‘generated’ its output. In modern patient centred care, clinicians strive to provide consumers with all the information and decision factors that are considered for their care.

Privacy and security: The developers of generative AI products rarely share the training database. Their policies are not clear on how their software captures and uses information provided by users. Most developers are international; it is unlikely that patient information captured would remain within Australia, and it is uncertain if information is stored in accordance with privacy and security legislation. Personal information, health information, sensitive information, unique identifiers, and other information cannot be shared without appropriate consent and data security obligations being fulfilled.

Appropriate use of artificial intelligence in health care

It is acknowledged that the innovation and development environment of generative AI is dynamic. Health services are encouraged to review the TGA advice about the regulation of software based medical devices to determine if the AI requires TGA ².

Health services should only consider generative AI following robust review of the potential benefits and harms and remain consistent with the most recent regulatory advice. In the interim, health services are advised to incorporate the oversight artificial intelligence oversight into their local new technologies committee terms of reference. Local policy should be developed regarding:

- Creation of an enrolment mechanism to register and approve staff user accounts to access generative AI platforms.
- Establishment of a process through which staff can report any use of generative AI that is unsafe or that contradicts these recommendations.

¹ <https://www.tga.gov.au/resources/artg>

² <https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/manufacture-guidance-specific-types-medical-devices/regulation-software-based-medical-devices>

- Provision of advisory material to staff on the risks when using generative AI

In addition:

- Publicly available generative AI platforms should only be used in cases where the risk of patient harm, financial jeopardy or information security breaches is low. The platforms should have passed TGA processes, unless there is no chance it would influence clinical outcomes.
- User inputs into unregulated generative AI tools must not include or reveal health information, sensitive information, classified information, unique identifiers, or personal information.
- All activities must align with applicable legislation and policies relating to information collection, use and disclosure and data security (notably the *Privacy Act 1988*, *Health Records Act 2001*). Staff should be informed of the legal ramifications if this legislation is not adhered to.

Appendices

1 – Definitions, background and further information

2 - TGA Regulation of Software as a Medical Device - Artificial Intelligence Chat, Text, and Language

Appendix I – Definitions, background, and further information

Definitions

Generative artificial intelligence is usually defined as software that can create novel content including (but not limited to) text, images, music, and computing code.

Generative AI tools are typically built on Large Language Models (LLMs) or Multimodal Foundation Models (MFM). These models use machine learning algorithms to predict an output – such as an image or word – based on an input, such as a sequence of words. LLMs generate human-like text outputs whereas MLMs can generate more complex outputs using wider range of inputs (speech, images etc.).

Background

While generative AI software has been available for some years, it was the emergence of new generative AI such as ChatGPT in late 2022 that caught the public attention. ChatGPT is publicly available, free to use and offers immediate benefit for users with relatively little effort. The uptake of ChatGPT has been unprecedented, taking just five days to reach 100 million registered users.

Artificial Intelligence in health has historically been analytical, the emergence of generative AI has challenged health services, system managers and regulators on how to embrace this new technology while ensuring that its use is safe and effective. To illustrate the issue, there are AI tools that can support clinicians in diagnosing disease. Generative AI could potentially use this information and create a treatment plan for that disease.

ChatGPT is the most prominent example of generative AI in the public domain at present, but others are expected to emerge within the year – notably Google’s “Bard” and Microsoft’s Windows ‘Co-Pilot”.

Further Information

For more information it is recommended that staff visit the following services:

- Digital Transformation Agency: Interim guidance for agencies on government use of generative AI platforms. <https://architecture.digital.gov.au/guidance-generative-ai>
- Australia Chief Science Rapid Response Information Report Generative AI: Language models and multimodal foundation models. https://www.chiefscientist.gov.au/sites/default/files/2023-06/Rapid%20Response%20Information%20Report%20-%20Generative%20AI%20v1_1.pdf
- Therapeutic Goods Administration. Regulation of software based medical devices: <https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/manufacture-guidance-specific-types-medical-devices/regulation-software-based-medical-devices>
- Australian Alliance for Artificial Intelligence in Healthcare. A Roadmap for AI in Healthcare for Australia. [A Roadmap for AI in Healthcare for Australia | Ai Health Alliance](#)
- the Royal Australian and New Zealand College of Radiologists’ Ethical Principles for AI in Medicine <https://www.ranzcr.com/college/document-library/ethical-principles-for-ai-in-medicine>

The following journal article discusses the broader picture of generative AI in health care:

- Coiera EW, Verspoor K, Hansen DP. We need to chat about artificial intelligence. Med J Aust. 2023 Jun 11. <https://www.mja.com.au/journal/2023/219/3/we-need-chat-about-artificial-intelligence>

Appendix 2 - TGA Regulation of Software as a Medical Device - Artificial Intelligence Chat, Text, and Language ³

Artificial intelligence text-based products like ChatGPT, GPT-4, Bard, and other large language models (LLMs) have recently received media attention.

When LLMs have a medical purpose and are supplied to Australians, they may be subject to medical device regulations for software and need approval by the TGA. It is important to note that regulatory requirements are technology-agnostic for software-based medical devices and apply regardless of whether the product incorporates components like AI, chatbots, cloud, mobile apps or other technologies. In these cases, where a developer adapts, builds on or incorporates a LLM into their product or service offering to a user or patient in Australia - the developer is deemed the manufacturer and has obligations under section 41BD of the [Therapeutic Goods Act 1989- external site](#).

The TGA has published guidance to help developers determine whether a product is a software-based medical device – the “Is my software regulated?” [flowchart on the TGA website](#) in addition to other guidance about [recent regulatory changes and boundary clarifications](#) for software and [FAQs](#).

Clinical and technical evidence will need to demonstrate the safety and performance of the product using the LLM to the same standard as other medical devices – for higher risk products, clinical and technical evidence are required to be more stringent

Technical requirements:

- Software developers will need to understand and demonstrate the sources and quality of text inputs used to train and test the model, and in clinical studies, in addition to showing how the data is relevant and appropriate for use on Australian populations.
- It is important to note that where there are no medical purpose or claims associated with the product using the LLM or if it does not meet the definition of a medical device as defined in the section 41BD of the [Therapeutic Goods Act 1989- external site](#), it is unlikely to be a medical device and is not regulated by the TGA.

Further information

The TGA has people dedicated to software and other challenges associated with regulating digital medical devices. If you have questions about the regulation of software or other digital medical technologies, please contact: digital.devices@tga.gov.au.

Note that, most software apps that are not medical devices are a consumer product and issues with these apps should be referred to the [Australian Competition and Consumer Commission- external site](#) (ACCC).

³ see [Regulation of software based medical devices | Therapeutic Goods Administration \(TGA\)](#)