Clarifying and strengthening the regulation of AI: Consultation paper by the Therapeutic Goods Administration (TGA)

RACGP submission October 2024

Background

The Royal Australian College of General Practitioners (RACGP) has prepared a response to the Therapeutic Goods Administration's (TGA's) consultation paper on the regulation of AI, released to the public for consultation in September.

The consultation paper can be viewed and downloaded via the TGA's consultation hub at https://consultations.tga.gov.au/tga/clarifying-and-strengthening-the-regulation-of-ai/.

The TGA has issued this consultation paper as part of the review of priority areas in the health and aged care sector which intends to ensure its existing legislative framework aligns with the guardrails proposed by the Australian Government Department of Industry, Science and Resources (DISR). The RACGP is concurrently preparing a response to DISR's proposals paper.

The RACGP has sought feedback from across the College on our draft response to the consultation paper.

The TGA has posed 20 questions pertaining to the paper, and has directed respondents to make their submissions through an online platform.

The TGA's introductory information and discussion questions are replicated below, together with the RACGP's proposed responses highlighted in blue. When finalised, the RACGP's response will be submitted via the online platform.

RACGP Practice Technology and Management team

Questions

Language and definitions

While definitions used in the *Therapeutic Goods Act 1989* may still adequately describe the entities and activities responsible at the appropriate time, stakeholders have indicated potential changes to the definitions would provide clarity and strengthen regulation. Examples of definitions that potentially could be recommended for change include:

- "Supply", to include language about the availability of software products from virtual platforms, for example website or app stores.
- "Manufacturer" to include the appropriate legal entity responsible for the development and deployment of software products that are medical devices.
- "Sponsor" to include a person who provides, hosts, or facilitates access to software products that are medical devices, particularly when they are accessible through data transfer or online platforms only.

Clarity is required for who is responsible and liable for the outputs of these systems, particularly when their activities constitute a breach of the Act or other laws.

1. Do you broadly agree that a review of the definitions in the Therapeutic Goods Act 1989 and subordinate legislation is needed to clarify responsibility for the development, deployment and use of AI models and systems?

Yes

No

2. Are there specific definitions that should be clarified?

Yes

No

If yes, what are they?

The definition of "manufacturer" should be clarified to give detail about who is responsible for fundamental changes to an AI model/system as a result of the process of machine learning. The role of a "manufacturer" of an AI model/system will be different from that of a drug manufacturer, as once a drug is released its function is typically static, whereas when an AI model/system is released, its function and scope can expand beyond its initial purpose.

3. Are there specific activities you are concerned would not be appropriately regulated using the existing legislation?

Yes

No

If yes, what are they?

N/A

Classification rules

Medical devices are regulated based on the risk they pose when used as intended. In Australia the risk posed by a device is determined using "classification rules". The classification rules are detailed in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002. There are specific rules for programmed or programmable medical devices or software that is a medical device which will apply to devices that are, or incorporate, an AI system or model.

AI-enabled devices are increasingly being used to predict clinical outcomes or provide prognostic information about a particular disease or treatment. The existing classification rules do not explicitly account for products intended for **prediction** or **prognosis**, meaning a default risk classification of Class I currently applies. This is not considered appropriate in cases where this information is used to determine treatment plans or interventions which could have a significant and detrimental impact on patients if the prediction or prognosis is not accurate.

A potential amendment of the current classification rules 4.5(1) and 4.5(2) to include prediction or prognosis would mean these devices would be classified at a higher level, depending on how serious

the disease or condition they are providing information about is and whether the information is being provided to a clinician or a consumer.

4. Do you agree that programmed or programmable medical devices or software that is a medical device for use in providing a prediction or prognosis in relation to a disease or condition should be reclassified under classification rules 4.5(1) and 4.5(2)?

Yes

No

Why or why not?

There is a sufficiently high risk to warrant upgrading the classification of AI models/systems involved in predicting disease and prognosis.

5. Are all other classification rules in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 appropriate for the risks associated with the use of medical devices that are, or incorporate, AI models and systems?

Yes

No

Why or why not?

The RACGP cannot foresee issues with the other classification rules.

6. Should there be specific classification rules for devices that are, or incorporate, AI systems or models?

Yes

No

If yes, what are they and why should they be introduced?

N/A

Essential principles

The essential principles are safety and performance requirements for all medical devices, including in vitro diagnostic (IVD) devices. These requirements are detailed in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002. Manufacturers must ensure their devices meet all relevant principles and sponsors must either hold or be able to obtain this evidence from their manufacturer on request.

Demonstrating compliance with the essential principles may include compliance with relevant international standards, but for emerging technologies where an appropriate standard may not yet exist, other approaches may be used. The flexibility to adapt the principles to the unique

circumstances of a medical device, particularly those incorporating emerging technologies, allows approaches to evolve over time without continuous review and updating of legislative frameworks.

The essential principles most likely to require amendment to address risks associated with medical devices that are, or incorporate, AI models and systems:

- Essential principle 12.1: Specific requirements for programmed or programmable medical devices or software that is a medical device.
- Essential principle 13: Information to be provided with all medical devices.

7. Are the current requirements in essential principle 12.1 sufficient to address the risks emerging from the complexity of the different subtypes of AI?

Yes

No

If yes, please provide details.

N/A

8. Are additional provisions required to address specific kinds of AI? (adaptive AI, generative AI, machine learning, etc)

Yes

No

If yes, what provisions and under which circumstances?

AI capabilities will continue to evolve and present harms that could not have been anticipated. It is difficult to protect against these harms and it is unclear how this could be addressed in the essential principles.

Additional provisions could also specify the need for transparency in the source of data and to detail risks associated with relying solely on the recommendations/information provided by an AI system.

9. Should there be additional provisions to ensure the ongoing performance of open-source software that is incorporated in medical devices?

Yes

No

If yes, please provide details.

Open-source applications might carry greater risks to safety as their models can be built on poor-quality/biased training data, and the quality of the data might be opaque to the user. Efforts to address these risks should be made in the essential principles (it is unclear whether this is already covered, for example in essential principle 12.1.6).

10. Should there be a requirement in the essential principles to identify when AI is incorporated in a medical device? (Check all that apply)

- When it is standalone AI as a medical device
- When it is used as part of the device achieving its intended purpose
- Where a specific kind of AI is being used (generative AI, adaptive AI, etc)
- Medical devices that are an AI system or model should be identified on the labelling and/or in the instructions for use
- Medical devices that use an AI system or model to generate data or make decisions about the care of a patient should be identified on the labelling and/or in the instructions for use
- Other circumstances (please elaborate)

11. Are there other risks associated with the use of AI that should be addressed with additional labelling requirements?

Yes

No

If yes, please provide information about what the risks are and what additional labelling requirements should be introduced.

N/A

Software exclusions

In 2021, changes to the Regulations commenced that "carved out" out a number of software-based products from TGA oversight on the basis that:

- they presented a very low risk to users; and/or
- they were not medical devices to begin with, and clarity was required for stakeholders; and/or
- existing oversight measures were available through other regulatory frameworks to ensure these products were safe and fit for their intended purpose.

These exclusions are detailed in the Therapeutic Goods (Excluded Goods) Determination 2018.

Since 2021 the TGA has been monitoring the exclusions and has received feedback from interested stakeholders, as well as through the targeted workshops that indicate the increasing complexity of some excluded software products and the increasing use of AI mean the exclusions may no longer be appropriate for:

- Consumer health products (Schedule 1, Item 14B)
- Digital mental health tools (Schedule 1, Item 14E)
- Software that is a calculator (Schedule 1, Item 14L)
- Laboratory information management systems (Schedule 1, Item 14O)

Potential options for change include:

1. Removing the exclusion for some of these kinds of products and regulating them under the medical device framework.

2. Removing the exclusion of these kinds of products and introducing an exemption for certain products (more information about exemption versus exclusion can be found on the TGA website here).

3. Changing the current conditions of exclusion for these kinds of products.

Exemption of products rather than exclusion provides a pathway to the supply of medical devices with a reduced regulatory burden for sponsors as exempt products are regulated by the TGA but are not required to be included in the ARTG before they are supplied. Advantages of this approach include the TGA's ability to take post-market action against these kinds of products when they do not meet the requirements for medical devices in terms of demonstrating safety, quality and performance; or where adverse events warrant a recall activity.

12. Do you think the existing software exclusions to carve out certain products from the Medical Devices Regulations remain appropriate?

a. **Consumer health products** Yes / No
b. **Digital mental health tools** Yes / No
c. **Software that is a calculator** Yes / No
d. **Laboratory information management systems** Yes / No

If no, what measures do you consider most appropriate for the identified exclusions? If yes, why?

Removing the exclusion of these kinds of products and introducing an exemption for certain products.

13. Are there other software exclusions you consider inappropriate?

Yes

No

If yes, what are they and why?

N/A

International harmonisation

The TGA is engaged in a number of key international activities, and where possible, seeks to align with approaches taken in other jurisdictions. Our current approach and commitment to international harmonisation is a key element to our regulation of therapeutic goods, allowing sponsors of medicines and medical devices to use international assessment and approvals from comparable overseas regulators to support applications for inclusion of their therapeutic goods in the ARTG. Mutual recognition and the ability to use evidence and certification from comparable overseas regulators streamlines the Australian process for sponsors who are bringing their therapeutic goods to market. These measures ultimately reduce costs and lead times for Australian consumers who are seeking access to therapeutic goods, without introducing unacceptable risks.

Stakeholders have indicated that:

1. International harmonisation of medical device regulation is a key feature underpinning the timely entry of innovative devices to the Australian market.

2. Failing to maintain international alignment is likely to delay or prevent the supply of some therapeutic goods to the Australian market as the cost of undergoing additional evaluation for entry to such a small market is likely to dissuade sponsors.

14. What risks and/or advantages do you see to maintaining international harmonisation?

Maintaining international harmonisation appears a sensible approach.

15. Are there circumstances where the risk posed by the use of AI models and systems should override international harmonisation?

Yes

No

If yes, what are they?

N/A

Transparency

Transparency has been raised as a consistent issue with the use of AI across all stakeholder groups, particularly consumers and clinicians, who would like to be able to identify the use of AI models and systems more easily.

Stakeholders (including consumers) are seeking information about:

- Whether a therapeutic good has been approved by the TGA.
- What information was used to support the approval to supply a therapeutic good.
- Any special conditions or limitations about the use of a therapeutic good.
- Easy identification of the ARTG inclusion for the therapeutic good, with links to publicly available information such as the product information, consumer medicine information, instructions for use, etc.
- For medical devices that are, or that incorporate AI models and systems – information about, or access to, the datasets that were used to train the AI.

Stakeholders have identified there is unlikely to be one approach that would adequately address the need for greater transparency. They have indicated the ability to identify the use of AI is more important where an AI model or system has been used to generate a result or propagate data that may require their review or input to ensure accuracy. For example, where a digital scribe product is suggesting a diagnosis based on the information provided during a consultation with the patient.

The following proposals are therefore not limited to the identification of AI models and systems either within specific medical devices or therapeutic goods more broadly, but also relate to the kinds of initiatives that could be taken to improve access to information about therapeutic goods:

- Publication of a list of approved medical devices that are, or use, AI on the TGA website, similar to that published by the FDA.

- Use of an identifying symbol or other mark, to show that a therapeutic good has been approved by the TGA.
- The ability to publish the ARTG number on therapeutic goods and to advertise or provide information about the regulatory status of products.
- Identification of devices that use AI within the ARTG public summary.
- Inclusion of product names for therapeutic goods in the ARTG public summary or other publicly accessible database.

16. Should therapeutic goods be labelled or identifiable as having met the TGA's regulatory requirements?

Yes

No

If yes, how should therapeutic goods be labelled? (Please check all that apply)

With a simple mark or symbol that shows that it is "TGA approved"

With the ARTG inclusion number

Through a publicly available database

Other (please explain)

17. Are there other measures the TGA should implement to improve transparency about the use of AI models and systems in therapeutic goods?

Yes

No

If yes, what are they?

N/A

Guidance, education, information and communication

During the targeted stakeholder workshops, a large number of participants were in agreement that the TGA's existing regulatory framework is already quite robust due to the flexibility afforded by its technology-agnostic approach. Stakeholders further noted that many of the issues associated with regulation of AI can be attributed to a lack of education, communication, information and guidance about how the existing framework is applied to therapeutic goods that incorporate AI models and systems.

The TGA has a number of guidance documents and assorted information available on our website to assist stakeholders with understanding how medical devices, including those that are or incorporate AI models and systems, including:

- Clinical evidence guidelines

- Real World Evidence guidance
- Is my software regulated?
- How the TGA regulates software based medical devices
- Excluded software
- Artificial intelligence (AI) and medical device software
- Software-based medical devices FAQs

18. Is the use of AI models and systems adequately covered by the current guidance and information available on the TGA website?

Yes

No

If no, what changes or additional material are required?

N/A

19. Are there places other than the TGA website where information about the regulation of therapeutic goods should be made available?

The RACGP can be approached to publish information relevant to our GP members through relevant internal media channels.

20. Are there specific resources that should be developed to support clinicians and consumers?

Yes

No

If yes, what are they and where should they be provided?

It would be appropriate to engage in a broader public campaign (eg waiting room posters, media advertising) to educate consumers and clinicians about how products using AI models and systems are regulated by the TGA.