Avant
By doctors for doctors

Avant Mutual Group Limited
ABN 58 123 154 898

Registered office
Level 6, Darling Park 3
201 Sussex Street, Sydney NSW 2000

Postal address
PO Box 746 Queen Victoria Building
Sydney NSW 1230

DX 11583 Sydney Downtown

avant.org.au

Telephone 02 9260 9000 **Fax** 02 9261 2921
Freecall 1800 128 268 **Freefax** 1800 228 268

11 October 2024

Therapeutic Goods Administration
Department of Health and Aged Care

Via the Consultation Hub

Clarifying and Strengthening the Regulation of Artificial Intelligence (AI)

Thank you for the opportunity to provide a response to the Therapeutic Goods Administration's consultation on Clarifying and Strengthening the Regulation of AI.

Our submission is attached.

Please contact me or Tracy Pickett on the details below if you require any further information or clarification of the matters raised in the submission.

Yours sincerely

Georgie Haysom
General Manager, Advocacy, Education and Research
Email: georgie.haysom@avant.org.au

Tracy Pickett
Legal and Policy Adviser
Email: tracy.pickett@avant.org.au

Avant submission to the consultation on Clarifying and Strengthening the Regulation of Artificial Intelligence (AI)

Avant is a member-owned doctors' organisation and Australia's largest medical indemnity insurer, committed to supporting a sustainable health system that provides quality care to the Australian community. Avant provides professional indemnity insurance and legal advice and assistance to over 90,000 healthcare practitioners and students around Australia (more than half of Australia's doctors). Our members are from all medical specialities and career stages and from every state and territory in Australia.

We assist members in civil litigation, professional conduct matters, coronial matters and a range of other matters. Our Medico-legal Advisory Service provides support and advice to members and insured medical practices when they encounter medico-legal issues. We aim to promote quality, safety and professionalism in medical practice through advocacy, research and medico-legal education.

General comments

Avant supports a risk-based approach to regulation of AI. We agree that the use of AI in health care is high-risk, based on the potential for adverse impacts on an individual's physical or mental health or safety.

Importantly however, there is a scale of risk for AI and AI-enabled products that might be used in health care. Uses range from providing and collecting information, triage and prioritisation, document summarisation, prediction and clinical decision support, to diagnosis, treatment, prognosis and ongoing clinical management.

Our view is that the regulatory settings for AI and AI-enabled products used in health care should be commensurate with the scale of risk associated with the product and its intended use. Not all uses need to be treated in the same way. A balance is required between regulation for safety and consistency, and promotion of innovation.

Where the definition of "medical device" under the Therapeutic Goods Act 1989 is met, a product should fall under the TGA's regulatory regime. This includes where a product incorporates prediction, clinical decision support, diagnosis, treatment, prognosis and ongoing clinical management.

We are concerned, however, about AI and AI-enabled products used in health care that are currently subject to no regulation if they do not meet the definition of "medical device" but still represent a higher level of risk for users (including consumers and clinicians). An example is AI scribes.

We believe there should be mandatory minimum standards for AI tools used in health care that fall outside the TGA's regulatory framework. As well as AI scribes, this should include consumer health products, digital mental health tools and any AI tools that suggest clinical findings and make recommendations that if not acted upon or if inaccurate could cause adverse patient outcomes.

We will provide further commentary in our submission to the Department of Health and Aged Care consultation on AI and welcome ongoing engagement with the TGA.

Response to consultation questions

Language and definitions

10. 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

11. Are there specific definitions that should be clarified? If yes, what are they?

- Yes
- No

We agree that a review of the definitions in the Therapeutic Goods Act 1989 (the Act) and subordinate legislation is needed to clarify regulatory responsibility where software and products that are or incorporate AI models and systems are therapeutic goods.

A key step in the review will be ensuring alignment with the definitions of “developer”, “deployer” and “end-user”, as outlined in the Department of Industry, Science and Resources paper, *Safe and Responsible Artificial Intelligence (AI) in Australia – proposal for introducing mandatory guardrails for AI in high risk settings* (DISR paper).

The potential for overlap between these roles should also be considered to avoid unintended consequences that might flow from the definitions.

For example, the Therapeutic Goods Administration’s consultation paper (TGA paper) includes the suggestion that the definition of “manufacturer” be amended to include the appropriate legal entity responsible for both the development and deployment of software products that are medical devices. The TGA paper also suggests that the definition of “sponsor” be amended to include a person who provides, hosts or facilitates access to software products.

Under definitions in the DISR paper, individual doctors may be both deployers and users of AI in settings such as medical practices. If the definitions of “manufacturer”, “sponsor” or “deployer” are too broad, they might inappropriately capture doctors using AI-based medical devices. The consequences of this are that doctors may have regulatory obligations under the Act and be liable to criminal offences and civil penalties for non-compliance, when they are not the appropriate legal entity responsible. They also may not have insurance cover as any liability for the product would be covered by the manufacturer of that product.

While we appreciate it may not be within the remit of the TGA, we note that there needs to be legal certainty around accountability, responsibility, and liability across the AI lifecycle in health care.

Currently, it can be difficult to determine who is accountable when AI-driven decisions result in errors or adverse unintended outcomes. The complexity of AI algorithms makes it challenging to trace the decision-making process, creating medico-legal risks and complicating the implementation of risk management processes and the assignment of liability.

There is a risk that responsibility for the design or function of AI could be unfairly shifted onto doctors. This has been exacerbated by the presence of broad indemnity clauses in some AI provider contracts, which attempt to absolve developers/providers of responsibility and liability and place the burden on doctors using the AI system. This gives rise to moral hazard, exposes doctors to legal risk, and raises concerns about whether their professional indemnity insurance will cover liability under such contracts.

In our submission to the Department of Industry, Science and Resources consultation, we have recommended that the mandatory guardrails should address this risk. There should be standards to ensure that the guardrail obligations for developers and deployers remain in force for the period that the developer or deployer maintains their involvement with the AI system. Developers and deployers should be required to ensure they have insurance to cover future liability. This is particularly important in the health sector given limitation periods under civil liability legislation.

12. Are there specific activities you are concerned would not be appropriately regulated using the existing legislation? If yes, what are they?

- Yes
- No

Existing legislation does not regulate AI scribes unless they meet the definition of “medical device” under the Act.

We understand that there are some AI scribes that perform tasks that amount to clinical decision support, diagnosis and prediction, but may not have been subject to the TGA’s regulatory oversight. There is an implied assumption that some of these tools are low-risk, but this is not necessarily the case.

Because there is no regulatory oversight of AI tools, such as AI scribes, that do not meet the definition of “medical device” under the Act, there is no objective consideration of whether these tools comply with current legislative and ethical requirements.

We believe there should be mandatory minimum standards for AI tools that fall outside the TGA’s regulatory framework. This should apply to AI scribes and, as outlined in our answer to question 21, should also include consumer health products, digital mental health

tools and any AI tools that suggest clinical findings and make recommendations that if not acted upon or if inaccurate could cause adverse patient outcomes.

The minimum standards would include:

- Privacy and security
- Transparency and explainability around how the tool works and has been trained
- Record keeping, access to metadata and access to historical data for relevant time periods
- Service agreements and the extent to which disclaimers and indemnity clauses can or cannot be used
- Controls in place to reduce the risk of patient harm.

Having an "approved" mark certifying that the tool meets mandatory minimum standards would provide reassurance to practitioners and patients and support safe adoption.

Standards development, accreditation and education may not be within the TGA's remit but could be within the remit of the Australian Commission on Safety and Quality Health Care or the Australian Digital Health Authority, or an AI regulatory body as referred to in the Department of Health and Aged Care's consultation paper on Safe and Responsible Artificial Intelligence in Health Care.

Classification rules

13. 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)? Why or why not?

- Yes
- No

Overall, Avant supports a risk-based approach to regulation of AI. We agree that the use of AI in health care is high-risk, based on the potential for adverse impacts on an individual's physical or mental health or safety. There is a scale of risk for AI and AI-enabled products that might be used in the health care setting, and the regulatory settings for AI and AI-enabled products used in health care should be commensurate with the scale of risk associated with the product and its intended use.

In line with this, we agree with the proposal (on page 11) to reclassify AI or AI-enabled products intended for prediction or prognosis at a higher level, depending on the seriousness of the disease or condition they are providing information about and whether the information is being provided to a clinician or a consumer. We also believe that a higher classification level is needed where the 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.

14. 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? Why or why not?

No response.

15. Should there be specific classification rules for devices that are, or incorporate, AI systems or models? If yes, what are they and why should they be introduced?

No response.

Essential principles

16. Are the current requirements in essential principle 12.1 sufficient to address the risks emerging from the complexity of the different subtypes of AI? If yes, please provide details.

- Yes
- No

Overall, we support the essential principles and the principles-based approach which provides flexibility and accommodates the broad complexity and diversity of medical devices regulated, including as new technologies like AI emerge.

We also broadly support the current requirements for programmed or programmable medical devices or software in essential principle 12.1 as they cover the safety and performance aspects that are of interest to clinicians.

However, some aspects may require reconsideration by the TGA – these are outlined in our responses to question 17 and question 19.

17. Are additional provisions required to address specific kinds of AI? (adaptive AI, generative AI, machine learning, etc) If yes, what provisions and under which circumstances?

- Yes
- No

Additional provisions should be considered for all kinds of AI that can evolve so that its purpose or use changes. In this circumstance there should be a provision for adverse event monitoring as well as sufficient ongoing monitoring of the AI for changes to use and changes to outputs which might require reconsideration by the TGA.

18. Should there be additional provisions to ensure the ongoing performance of open-source software that is incorporated in medical devices? If yes, please provide details.

- Yes
- No

No response.

19. 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)

20. Are there other risks associated with the use of AI that should be addressed with additional labelling requirements? If yes, please provide information about what the risks are and what additional labelling requirements should be introduced.

- Yes
- No

We regularly receive requests from our doctor members wanting to know which AI scribe/s they should use and which meet the various requirements that we recommend they check for before starting to use an AI scribe (at this link: https://avant.org.au/resources/ai-scribes-a-checklist-of-things-to-consider).

When deploying and using AI, doctors have demonstrated that they want:

- confidence that the AI does what it purports to do, is reliable, explainable and secure, and will protect their patients' data
- someone to tell them what AI system to use (in the AI scribe context)
- systems that are evidence- based and clinically relevant and have been subject to clear approvals
- confidence they are covered by insurance if something goes wrong.

Having an "approved" mark of assurance and certification from the TGA (or other appropriate body) would provide reassurance for medical practitioners and their patients of regulatory compliance.

Software exclusions

21. Do you think the existing software exclusions to carve out certain products from the Medical Devices Regulations remain appropriate? If no, what measures do you consider most appropriate for the identified exclusions? If yes, why?

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

We agree that increasing complexity means that some consumer health products and digital mental health tools are no longer a general consumer good and now may meet the definition of “medical device” and require regulation.

Similarly, we agree that increased product functionality has seen scope creep beyond the intended purpose and, with this, the introduction of a higher level of risk for users. Many developers are not recognising this shift and therefore not seeking approval.

Our view is that the regulatory settings for AI and AI-enabled products used in health care should be commensurate with the scale of risk associated with the product and its intended use. Not all uses need to be treated in the same way.

Where a product, whether a consumer health product, digital mental health tool or other AI-based product, meets the definition of “medical device”, it should fall under the TGA’s regulatory regime. This includes where a product incorporates prediction, clinical decision support, diagnosis, treatment, prognosis and ongoing clinical management.

We are concerned, however, about AI and AI-enabled products used in health care that are currently subject to no regulation if they do not meet the definition of “medical device” but still represent a higher level of risk for users (including consumers and clinicians).

As noted in answer to question 12, we believe there should be mandatory minimum standards for AI tools used in health care that currently fall outside the TGA's regulatory framework. This should include consumer health products, digital mental health tools, AI scribes, and any AI tools that suggest clinical findings and make recommendations that if not acted upon or if inaccurate could cause adverse patient outcomes.

Our position is that further education of developers is also required. Please refer to our response to question 28.

22. Are there other software exclusions you consider inappropriate? If yes, what are they and why?

No response.

International harmonisation

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

No response.

24. Are there circumstances where the risk posed by the use of AI models and systems should override international harmonisation? If yes, what are they?

No response.

Transparency

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

- Yes
- No

26. 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)

27. Are there other measures the TGA should implement to improve transparency about the use of AI models and systems in therapeutic goods? If yes, what are they?

- Yes
- No

Guidance, education, information and communication questions

28. Is the use of AI models and systems adequately covered by the current guidance and information available on the TGA website? If no, what changes or additional material are required?

- Yes
- No

While the guidance and information on the TGA website is helpful and adequate to explain the current regulatory framework, further education and communications about the use of AI models and systems in health care would be useful. Based on feedback from our members, many have a limited understanding of AI generally.

Developers and deployers need tailored education and communications to understand their obligations and the potential risk to patients, particularly when they increase the complexity or functionality of AI and AI-enabled products.

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

We are not aware and would recommend engaging with developers and their representative bodies about where they would go for information.

30. Are there specific resources that should be developed to support clinicians and consumers? If yes, what are they and where should they be provided?

- Yes
- No

Clinicians would benefit from targeted education and communications from the TGA about the respective responsibilities of developers and deployers of AI and AI-enabled products. This would help them understand whether they fall within the relevant definitions and have any regulatory obligations, as well as evaluate whether it is appropriate to use any particular product.

This could include information about what a “TGA approved” mark or labelling means and the regulatory process it has been through to achieve this.

Avant has developed education resources for its members about the safe use of AI and AI-enabled products in health care settings These resources are available at this link: https://avant.org.au/artificial-intelligence-what-you-need-to-know.

Avant Mutual
11 October 2024