

TGA consultation: Clarifying and strengthening the regulation of Artificial Intelligence (AI)

Review of therapeutic goods legislation

Medical Technology Association of Australia

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Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology (MedTech) industry. MTAA aims to ensure the benefits of contemporary, innovative, and reliable medical technology are delivered effectively and sustainably to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of MedTech used in the diagnosis, prevention, treatment and management of disease and disability. The MedTech industry is diverse, with medical products ranging from frequently used items such as syringes and wound dressings, through to high-technology implantable devices such as pacemakers, defibrillators, bone and joint replacements, and other digital health products and services.

MTAA members provide Australia's healthcare professionals with essential product information, continuing education, and training to ensure safety and to optimise the effective use of MedTech. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia.

Executive Summary

MTAA welcomes the opportunity to comment on the *Therapeutic Goods Administration (TGA) consultation: Clarifying and strengthening the regulation of Artificial Intelligence (AI) - Review of therapeutic goods legislation* consultation paper. Australia has a proud record in medical device technology innovation. Artificial Intelligence (AI) and Machine Learning (ML) play an integral part in a growing number of MedTech related products and services. To provide a sector-wide perspective on AI, MTAA has incorporated the input of both member and non-member companies into this response to this therapeutic goods legislation review.

As recognised in the MTAA digital health report “Digital Health: Breaking Barriers to Deliver Better Patient Outcomes”, current applications of AI/ML in healthcare including clinical decision support, remote monitoring, and robotic surgical procedures are seeing substantial growth. 45% of respondents to the 2023 MTAA Digital Health survey reported that they plan to lodge additional AI/ML enabled applications with the TGA over the next five years.

International harmonisation is an aspect that needs to be considered carefully to ensure that no additional regulatory burden for the Australian market is introduced. The Australian market size is approximately 2% of the global healthcare market and any additional regulatory burden presents a real threat that Australia becomes an undesirable market for the development or release of AI enabled solutions. Alignment with organisations such as the International Medical Device Regulators Forum (IMDRF) for Medtech will ensure consistency and avoid duplication and additional regulatory burden.

Responses are limited to the current understanding with the restricted data provided in the TGA consultation. Additional consideration and substantial consultation with the MedTech industry must occur regarding any proposed regulation changes before implementation.

Questions

While there was the option to answer many of the discussion questions via Yes/No, MTAA believes that the complexity and nuance required to adequately express the opinion of the MedTech industry on some questions warrants full text-based responses.

Definition and language questions

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?

No

MTAA does not believe 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. The current framework and existing definitions of medical devices are flexible enough to accommodate the evolving use of AI. Any additional nuances can be effectively addressed through guidance documents rather than a regulatory change.

However, if there are changes that are deemed appropriate, extensive stakeholder consultation and review is essential. Any changes need to be aligned with international harmonisation which is crucial in ensuring there is no additional regulatory burden and continued patient access to essential medical technologies.

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

As an observation, the term “deployer,” as defined by DISR, has a broader meaning compared to “distributor” or “sub-contractor” under medical device regulations. Similarly, the term “end user” per the DISR definition is broader than the concept of the intended user under medical device regulations. Additionally, the definition of “supply” requires further clarification, particularly regarding open-source software, software platforms, and cross-border data flow, to ensure alignment with the specific context of medical device regulations.

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

While we are not concerned about any specific activities, it is essential to provide education to stakeholders about which AI solutions are classified as medical devices based on their intended purpose. Regulatory oversight should focus on the intended use and associated risks of the device, rather than the specific technology (e.g., AI) it incorporates. This ensures a consistent, risk-based approach to regulation, preventing unnecessary scrutiny purely because AI is involved, and focusing on patient safety and device efficacy.

Classification rules questions

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?

No

MTAA does not agree that reclassification is necessary. Rule 4.5(1) and 4.5(2) already classify software that provides diagnostic information according to the level of risk, and this approach should remain unchanged. Products intended for prediction or prognosis should be considered as part of diagnostic information under the current classification system. Any nuances can be effectively addressed through guidance documents and education, rather than altering the existing rules.

To reiterate, international harmonisation is crucial to avoid imposing additional regulatory burdens and to ensure continued patient access to essential medical technologies.

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?

Yes

The incorporation of AI models and systems should not affect how a device is classified, as classification should remain based on the principle of risk. Devices that use AI but have the same intended purpose as those without AI should not be treated differently. The focus of regulation should be on the outcomes and performance of the AI system, ensuring that it meets safety and efficacy standards, rather than on the specific technology it uses. This approach ensures consistency in regulation without adding unnecessary complexity for technology which is inevitable with the increasing use of AI.

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

The incorporation of AI models and systems should not impact how devices are classified. As above, classification should remain based on the principle of risk. The TGA should focus on maintaining consistent rules across different technologies rather than creating AI-specific classifications. Given the rapid pace of AI advancements, establishing specific classification rules for AI could quickly become outdated as new techniques emerge. A flexible, principles-based approach as is the current state is better suited to adapt to technological innovation.

We recommend the current classification system, which is based on the risk posed by the device's intended use, should still apply to AI-enabled devices without requiring separate classifications. Additionally, the existing rules for programmed or programmable medical devices and software are already aligned with the IMDRF classifications framework, supporting international harmonisation. Introducing any additional/different TGA AI-specific classification rules would pose a threat to Australian patient access.

Essential principles questions

Are the current requirements in essential principle 12.1 (Attachment B) sufficient to address the risks emerging from the complexity of the different subtypes of AI?

If yes, please provide details.

Yes

The current requirements in Essential Principle 12.1 (Attachment B) are sufficient to address the risks emerging from the complexity of various AI subtypes. These principles provide a comprehensive and adaptable framework, ensuring safety and performance in medical devices that incorporate AI, while still allowing for flexibility and innovation across different AI technologies.

The existing regulatory requirements remain applicable to AI-enabled devices, regardless of the specific AI subtype used. The current framework is robust and has been developed with international harmonisation in mind, ensuring that AI-enabled devices comply with global safety and performance standards. Importantly, the transparency of AI technology can be achieved within the existing principles, without needing additional regulatory changes.

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?

No

Additional provisions are not necessary at this time. The current framework is comprehensive, adaptable, and capable of addressing the risks associated with AI in medical devices while ensuring safety and performance. It also provides the flexibility required to accommodate innovation across various AI subtypes.

While we appreciate that adaptive AI can introduce unique risks, these can be effectively mitigated through mechanisms in the existing framework such as robust risk management and post-market monitoring processes. Additionally, given that the use cases and regulatory landscape for generative AI are still evolving, we recommend waiting for further experience and evidence before implementing any additional provisions.

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.

No

The existing framework does not require additional provisions to ensure the ongoing performance of open-source software that is incorporated in medical devices. Any open-source software incorporated in medical devices are already captured as a part of SOUP/OTS management by the developer and is required under ISO/IEC 62304. This includes assessing risks and changes of open-source software.

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

- o When it is standalone AI as a medical device.
- o When it is used as part of the device achieving it's intended purpose.
- o Where a specific kind of AI is being used (generative AI, adaptive AI, etc).
- o Medical devices that are an AI system or model should be identified on the labelling and/or in the instructions for use.
- o 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.
- o Other circumstances (please elaborate).

No

Any additional identification or labelling requirements should not be based on the technology itself but rather on a careful assessment of the risks. If specific risks are identified that require mitigation through labelling or Instructions for Use (IFU), then appropriate measures should be implemented. This is how labelling is currently managed for medical devices, and there should be no additional, more onerous requirements for AI-enabled medical devices. The focus should remain on risk-based regulation, ensuring patient safety without imposing unnecessary burdens on developers of technologies that incorporate AI but are still identified as low risk.

Other points to consider include:

- Labelling every device with AI could overwhelm users with unnecessary information. Labels should focus on critical risks and safety implications, not just the presence of AI, so users can concentrate on key safety and efficacy concerns.
- In some cases, AI is a secondary feature, like for data organisation or error-checking, and doesn't impact a device's main function. Requiring labelling for all AI functions would be unnecessary where AI poses little or no risk. A risk-based approach ensures labelling is only needed when AI affects safety or performance.
- Mandating AI labelling could cause confusion, as other technologies with similar risks, like algorithm-based tools, wouldn't need the same labels. A risk-based approach ensures consistency across all devices, regardless of the technology used.
- Mandating labelling for all AI devices, regardless of risk, could stifle innovation. Developers may avoid using AI in low-risk devices due to the extra regulatory burdens of labelling.

In addition, there are potentially two aspects to this: products used directly by consumers and those used by healthcare professionals (HCPs) on consumers. When a product is used by consumers directly, detailed warnings may be necessary, as they rely on the product's outcomes for decision-making. However, for products used by HCPs, the existing framework is sufficient. HCPs have the expertise to interpret the information, whether AI-driven or not, and their informed decisions lower the risk.

Rather than labelling every AI component upfront, AI-related information could be included in the Australian Register of Therapeutic Goods (ARTG). This will provide a clear database for people to check if a product uses AI, avoiding unnecessary labelling regulatory burden.

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.

No

Labelling should be technology-neutral and focus on clinical outcomes and risks rather than the specific technology used. This avoids bias toward certain technologies like AI and ensures safety concerns are addressed uniformly across all devices, whether they use AI or not.

Software exclusions questions

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

- a. Consumer health products
- b. Digital mental health tools
- c. Software that is a calculator
- d. Laboratory information management systems

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

Yes

MTAA believes the current exclusions remain appropriate, and should continue to be technology-agnostic, risk-based and based on the intended use, rather than on the underlying technology.

Further clarification and examples can also be provided through guidance documents. For instance, additional clarification regarding the exclusion criteria for consumer health products and software could be helpful as these technologies evolve.

International harmonisation questions

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

While MTAA understands that regulators must maintain the ability to address risks that are unique to their specific jurisdictions, maintaining international harmonisation is critical. Alignment with international standards, such as those from the International Medical Device Regulators Forum (IMDRF) ensures timely access of innovative AI-enabled devices for Australian patients.

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

No

The TGA, along with the efforts of the IMDRF and the Software AI Working Group, have already considered the risks associated with the use of AI. It is important that these existing frameworks are upheld and not overridden and introducing any Australian specific requirements, as maintaining international harmonisation remains a priority to ensure timely access for patients.

Transparency questions

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

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

- o With a simple mark or symbol that shows that it is "TGA approved".
- o With the ARTG inclusion number.
- o Through a publicly available database.
- o Other (please explain).

No

MTAA does not support therapeutic goods be labelled or identifiable as having met the TGA's regulatory requirements. Being on the ARTG is an indicator that therapeutic goods have met the TGA's regulatory requirements. Any additional requirements would create unnecessary burden for manufacturers. The Unique Device Identification (UDI) database, currently being implemented can be leveraged as a tool to verify whether a product is included on the ARTG. By utilising UDI system, users and healthcare professionals can easily confirm a product's registration status, helping to ensure transparency and trust in medical devices, including those incorporating AI.

Australia's small market size (~2% of the global healthcare market) means that imposing specific labelling requirements solely for Australia would create unnecessary overhead for international manufacturers. This could threaten patient access if manufacturers decide not to supply products due to such onerous requirements. Additionally, a single device may be supplied by multiple sponsors, each with its own ARTG number. Requiring all these numbers to be displayed on the device would present significant logistical challenges.

We do however support more education supported by the government to educate Australians about TGA, medical devices and the overall use of AI in the broader economy. Along with the potential for the development of a database that identifies devices containing AI such as the FDA's <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>. This could also take the form of ARTGs identifying devices that incorporate AI.

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?

As noted above, the ARTG database could be used to improve transparency by identifying devices that incorporate AI. This approach would facilitate transparency without imposing undue regulatory burdens on manufacturers.

Guidance, education, information and communication questions

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?

While the current guidance and information available on the TGA website covers aspects of AI in medical devices, there is a need for more comprehensive education on AI as a technology in general. The rapid advancements in AI require broader public and professional awareness, particularly regarding how AI is used in medical devices and how it is regulated to be safe and effective.

While it is part of the TGA's responsibility to provide clear and accurate regulatory guidance, government-led education efforts are crucial in ensuring that citizens understand AI and can trust its applications, including in medical devices. This education should focus on increasing knowledge of AI, its benefits, and the safeguards in place to ensure safety and effectiveness.

By promoting a better understanding of AI, the government can help foster trust in AI technologies, empowering the public and healthcare providers to make informed decisions. Therefore, it would be beneficial for the TGA and other government bodies to collaborate on wider initiatives aimed at educating the community about AI, helping to bridge the gap between innovation and public confidence and trust.

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

Social media, community forums, and educational institutions can serve as platforms to engage the public.

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

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

As above, more educational material to inform the public about how the regulations for AI in medical devices are designed would be helpful. These regulations are based on broad principles that already account for different technologies, including future advances like AI.

To make this information accessible, it's important to use clear, simple language and avoid technical jargon. Infographics, short videos, and interactive tools can effectively explain regulatory principles and their real-world implications for the public. This approach can ensure the information resonates with a wider audience, making complex topics more digestible.

Multiple communication channels should be utilized to reach various demographics. Social media, community forums, and educational institutions can serve as platforms to engage the public. Additionally, partnering with schools to include AI and digital literacy education, as suggested in the "Australian Framework for Generative AI in Schools", can help younger generations understand these technologies from an early age.

Moreover, it's crucial to provide context on AI's capabilities and limitations. Educating the public about what AI can and cannot do will help people understand why certain regulatory principles are necessary. Addressing common misconceptions about AI and fostering a more informed public discourse will help build trust and ensure that the public can engage with AI technologies confidently and safely.

Conclusion

MTAA commends the TGA on these efforts clarifying and strengthening the regulation of Artificial Intelligence (AI). MTAA and our members believe that the existing legislative regulatory framework adequately addresses the needs of medical device related AI. Additional training, guidance and education on the topics covered in this consultation is welcomed by industry, providers and consumers alike.

MTAA looks forward to the continued collaboration and engagement on the regulation of AI within therapeutic goods. We welcome further discussions and appropriate consultations with the TGA as legislation evolves in this fast-developing area.