

Safe and responsible AI in Australia

**Proposals paper for introducing
mandatory guardrails for AI in
high-risk settings**

**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 all of 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 *Safe and Responsible AI in Australia* Proposals paper for introducing mandatory guardrails for AI in high-risk settings. 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. In order to provide a sector wide perspective on AI, MTAA has incorporated the input of both member and non-member companies into this response to the Department of Industry, Science and Resources (DISR) discussion paper by way of a dedicated AI Working Group.

DISR has recognised the opportunity to place Australia as world leader in the responsible use of AI and this consultation paper provides options for AI use in high-risk settings. As healthcare is a predominantly high-risk setting, the MedTech industry is deeply invested in these potential mandatory guardrails. AI is poised to offer advantages across all sectors of the economy, and to public and private organisations of all sizes. MTAA welcomes the chance to provide input on the specific AI aspects that affect the healthcare sector and MedTech industry.

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 Therapeutic Goods Administration (TGA) over the next five years.

AI is not new to healthcare with many approved medical devices currently utilising the technology. As the use of AI in healthcare increases, new regulatory challenges will emerge, and regulation should adapt accordingly. For relevant technologies, the TGA, Australia’s medical device regulator, is best positioned to incorporate emerging AI regulation within their existing robust medical device assessment and regulation framework. Existing TGA medical device regulatory requirements, based on the *Therapeutic Good Act 1989* and subsequent regulations, are technology-agnostic with the overarching aim of safe and effective medical devices placed on the market. This includes software-based medical devices and those that include AI.

It is important to distinguish between AI in health that is covered by current TGA regulation and those, such as wellness apps or medical information software, that is not covered. The former type of AI should continue to be governed by the TGA’s current legislative and regulatory regime. The latter type, which presently has little or no regulation, requires further attention proportionate to the risk. Most products MTAA members provide, are or will be regulated by the TGA under existing legislation.

Due to the unique, complex, and highly regulated nature of MedTech, any broad regulation of AI, even regulation of AI aimed at the medical industry generally, could have unintended consequences for patient outcomes and restrict access to medical technology. 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.

Key learnings should also be taken from the recent changes to AI regulatory measures put in place in other jurisdictions. Australia should avoid any scenario that introduces duplication, confusion or additional regulatory burden in medical device regulation. A pertinent example is the introduction of the EU AI Act which has led to confusion and overly burdensome regulatory efforts impacting MedTech innovation and accessibility. MTAA strongly supports TGAs expertise and established frameworks for the regulation of AI enabled medical devices.

International harmonisation is another aspect that needs to be considered carefully to ensure that no additional regulatory burden for the Australian market is introduced. Alignment with organisations such as the International Medical Device Regulators Forum (IMDRF) for Medtech will ensure consistency and avoid duplication and additional regulatory burden.

Substantial consultation with the MedTech industry must occur regarding any proposed regulation changes.

MTAA has developed a comprehensive response to the TGA Consultation *Clarifying and strengthening the regulation of Artificial Intelligence (AI)* Review of therapeutic goods legislation, and we refer DISR to this response for additional details of the MedTech industry's views on AI regulation.

Discussion 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 the proposed mandatory guardrails demands full text-based responses.

Proposed principles

1. Do the proposed principles adequately capture high-risk AI?

The proposed principles are broad and capture high-risk AI use cases. However, this broad scope leaves the principles open to interpretation. As proposed, the burden of risk classification lies with the developer and their understanding of the principles which may lead to unintended consequences such as capturing low-risk use cases as high-risk, software and algorithms that are not true AI/ML, stifling MedTech innovation and ultimately patient access.

Further guidance &/or definitions as to what is classified as high-risk taking into consideration additional nuances and specificity is required. A risk assessment or management approach in line with internationally recognised standards such as ISO 13485 – Medical Devices – Quality management systems – Requirements for regulatory purposes - and ISO 14971 – Medical Devices – Application of risk management to medical devices remain useful in defining high-risk.

This is covered in more detail within the MTAA response to the related TGA Consultation - *Clarifying and strengthening the regulation of Artificial Intelligence (AI)*.

Categories of uses to be treated separately

Categories of use including defence, military, national security, mass surveillance, and weaponry should be considered separately and require a high level of scrutiny.

2. Do you have any suggestions for how the principles could better capture harms to First Nations people, communities and Country?

MTAA supports the need for specific consultation with First Nations people, communities and leaders to ensure potential harms are captured.

3. Do the proposed principles, supported by examples, give enough clarity and certainty on high-risk AI settings and high-risk AI models? Is a more defined approach, with a list of illustrative uses, needed? If you prefer a list-based approach (similar to the EU and Canada), what use cases should we include? How can this list capture emerging uses of AI? If you prefer a principles-based approach, what should we address in guidance to give the greatest clarity?

A principles-based approach, similar to the TGA Essential Principles (EPs), is the preferred option for the MedTech industry as it allows for emerging uses of AI. Additional clarity could be provided with a non-exhaustive list of high-risk use cases as a supplement to the principles, similar to the Therapeutic Goods (Excluded Goods) Determination 2018. The use case list could be provided as examples in guidance documents rather than the regulation to allow for flexibility.

Few healthcare relevant examples have been provided and would be a welcome addition. Further consultation with the healthcare sector is required before any approach is chosen to ensure there is no stifling of innovation or patient access to MedTech technologies.

4. Are there high-risk use cases that government should consider banning in its regulatory response (for example, where there is an unacceptable level of risk)?

Outright bans of any technologies or use cases should be avoided. Individual assessment of intended use and outcomes is required to appropriately determine that there is an unacceptable level of risk.

Use cases that allow the identification or impersonation of others such as facial recognition, sexual content, national security, military and defence should be addressed separately and require careful consideration for each specific technology and use case.

5. Are the proposed principles flexible enough to capture new and emerging forms of high-risk AI, such as general-purpose AI (GPAI)?

The proposed principles are broad and may be used to capture new and emerging forms of AI such as GPAI. However, the application of the principles to GPAI may limit the use, or development of GPAI and other new technologies in specific fields such as healthcare, if the intent, the level of severity, adverse impact, and autonomy are not taken into consideration. The ability to review and potentially extend and/or revise the principles is essential to ensure ongoing relevance as AI evolves.

There is the potential for every AI model to be considered high-risk and GPAI as they become the model of choice for all scenarios. A GPAI model can be used to build a specific use case, or a model can be built or fine-tuned for a specific use case, blurring the line between all AI.

6. Should mandatory guardrails apply to all GPAI models?

As stated above, guardrails may be difficult to apply for GPAI without consideration of a specific use case(s). Requirements for extensive testing across diverse use cases could be burdensome to developers and could stifle innovation (2 & 4).

Definitions of guardrail elements such as *end-users* may require additional clarification. If it remains as currently defined, the requirement of informing end-users would be overly burdensome and difficult to apply (6).

7. What are suitable indicators for defining GPAI models as high-risk?

For example, is it enough to define GPAI as high-risk against the principles, or should it be based on technical capability such as FLOPS (e.g. 10^{25} or 10^{26} threshold), advice from a scientific panel, government or other indicators?

It is the view of most companies MTAAs consulted that high-risk GPAI models should be defined against the principles rather than specific technical capabilities like FLOPS. This is important to capture emerging technologies where technical capabilities are as yet undefined. However, this view was not universal and the use of FLOPS in the US was considered very positive by a smaller sub-set of companies.

Guardrails ensuring testing, transparency and accountability of AI

8. Do the proposed mandatory guardrails appropriately mitigate the risks of AI used in high-risk settings?

Specifically for a medical device as defined by the regulations, these guardrails mimic the current approaches by the TGA to ensuring only safe and effective products are on the market.

There are multiple applications of GPAI in the delivery of healthcare services and the use of AI within a healthcare enterprise. These applications within health enterprises are not all at the same level of risk which needs consideration in the context of the guardrails. For example, the implementation of AI-guided customer service chatbots from a hospital, insurer, healthcare practice or MedTech company enhances efficiency of customer service rather than actual medical services. In this case, it would be inappropriate to subject mandatory guardrails to these implementations. However, if appropriately identified as “high risk”, TGA’s current framework is sufficient to address and mitigate this risk.

In addition, guardrails can only mitigate known and identified risks. An ongoing and total lifecycle risk management approach as is currently implemented in the medical device legislation (e.g. ISO 14971) is also required to adequately mitigate risks.

Further clarity of how the guardrails will deal with those health-related devices (not ARTG medical devices or excluded/exempt) is required. As covered in more detail within the MTAA response to the TGA Consultation - *Clarifying and strengthening the regulation of Artificial Intelligence (AI) Review of therapeutic goods legislation*.

9. How can the guardrails incorporate First Nations knowledge and cultural protocols to ensure AI systems are culturally appropriate and preserve Indigenous Cultural and Intellectual Property?

MTAA supports the need for specific consultation with First Nations people, communities and leaders to ensure AI systems are culturally appropriate and preserve Indigenous Cultural and Intellectual Property. Specific guidelines for proper use of Indigenous data and cultural information may be required.

10. Do the proposed mandatory guardrails distribute responsibility across the AI supply chain and throughout the AI lifecycle appropriately?

For example, are the requirements assigned to developers and deployers appropriate?

There is a potential that the proposed guardrails skew the responsibility up the supply chain. We believe the responsibilities need to be shared among all stakeholders appropriately otherwise there is a risk that the Australian market becomes unattractive resulting in patients missing out on valuable life-saving and life-enhancing technology.

The intended use and design must be considered as many solutions can be utilised in ways and methods unknown to the original developers. End users have the ability to leverage systems for unintended purposes and must bear appropriate responsibility for potential adverse consequences. This is the current situation with medical devices on the Australian market enforced by TGA.

Moreover, data quality, especially for the data used to train models, may often be out of the control

of individual developers. Deployers and integrators of these technologies must take responsibility for these changes.

The TGA has requirements in place for personalised medical devices and point of care manufacturing that can provide a useful resource in this area

<https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/point-care-manufacturing-medical-devices>.

In addition, the ability to ensure regulatory oversight and enforcement across the AI supply chain, including cross-border data flows and cross-border AI model deployment is required.

11. Are the proposed mandatory guardrails sufficient to address the risks of GPAI?

As per the response to question 8, a risk management approach, similar to what is applied by TGA, is required to appropriately mitigate the risks of GPAI.

12. Do you have suggestions for reducing the regulatory burden on small-to-medium sized businesses applying guardrails?

Regulatory burden is a major concern for all sized businesses. Given the Australian market size is approximately 2% of the global healthcare market, any additional regulatory burden presents a real threat that Australia becomes an undesirable market for the development or release of AI enabled solutions.

The key to reducing regulatory burden is international harmonisation principles and global standards such as ISO 42001. Additionally, in the case of medical devices using AI, aligning with frameworks developed by organisations such as the International Medical Device Regulators Forum (IMDRF) will ensure there are minimal additional requirements for the local market. This will also ensure patient access to MedTech is not adversely impacted.

Clear guidelines, education, and training will help businesses especially small-to-medium sized ones comply with regulations.

Sandbox activities and facilities available for small businesses and developers would also be a useful option. The CSIRO regulatory sandbox project “allows for the testing of innovative AI products in a real-world setting, with relaxed regulatory requirements, on a time-limited basis, at a smaller scale, and with appropriate safeguards in place” and is a welcome initiative in this space <https://research.csiro.au/ss/science/projects/responsible-ai-pattern-catalogue/regulatory-sandbox/>

Regulatory options to mandate guardrails

13. Which legislative option do you feel will best address the use of AI in high-risk settings?

For the MedTech industry, the key is to continue regulation of medical devices (technologies which seek to achieve a diagnostic or therapeutic benefit) via the current regulator (TGA), and ensuring the work and processes already in place and functioning well around SaMD are continued. There is no need for wholesale revisions to the regulation that is in place and working effectively. Harmonisation with other key markets is key to ensure that no additional regulatory burden for the Australian market is introduced.

Options 1 and 2 are options that would work for the MedTech industry, enabling the existing TGA framework, definitions and technology-agnostic essential principles to remain in place. Australia is a very small part of the global healthcare market and continuing to harmonise via the International Medical Device Regulatory Forum (IMDRF) is crucial.

Option 2, a framework approach would be an appropriate legislative option to address AI in high-risk settings. A framework approach will support the safeguarding of AI in certain use cases and also allow innovation in other areas without the regulatory burden. As new use cases emerge with evolving technologies, a new framework may be developed to encapsulate these advancements. With TGA remaining as the sole regulator for medical devices avoiding any significant additional regulatory burden.

Option 1, a domain specific approach could also achieve these goals, and we have seen within the TGA Consultation - *Clarifying and strengthening the regulation of Artificial Intelligence (AI) Review of therapeutic goods legislation* how the TGA has mapped existing regulation via the risk-based framework, QMS, essential principles, post-market monitoring and conformity assessment, essential principles to the guardrails showing no further regulatory overlay may be required for medical devices. There are minor concerns with the number of changes required and the timing and sequencing of these changes.

Option 3, a whole economy approach is the least favourable and can have negative impacts. In the EU, the introduction of the AI Act has led to additional regulatory burden on manufacturers. This needs to be avoided in Australia to ensure that innovation is not stifled, and patient access is not hindered. A cross-economy AI Act is not appropriate given the fast-evolving nature and wide use of AI.

Once an Australian approach is selected, additional consultation with the healthcare sector is essential to ensure that specific healthcare nuances are considered.

14. Are there any additional limitations of options outlined in this section which the Australian Government should consider?

Any duplication or addition of regulations should be avoided. The introduction of the EU AI Act has introduced both confusion and burdensome regulatory efforts impacting MedTech innovation and accessibility.

If a whole of economy approach (Option 3) is undertaken, there may be significant delays to market access of medical device products, as currently being experienced in the EU.

15. Which regulatory option(s) will best ensure that guardrails for high-risk AI can adapt and respond to step-changes in technology?

Option 2, the framework approach and Option 1, a domain specific approach would be good options to ensure that guardrails can adapt to step-changes in technology.

16. Where do you see the greatest risks of gaps and inconsistencies with Australia's existing laws for the development and deployment of AI?

Issues around data access, transfer and privacy will need to be addressed along with the regulation of AI. Cross-border data flows and AI model deployment, data privacy and quality are other areas that require further development.

Additional Information

The large number of emerging AI solutions already in and entering the marketplace will make compliance a challenge for any regulator. The capability and capacity of any regulator needs to be addressed to ensure that the regulations are adequately enforced. Upskilling and expansion of any regulator, new or existing, will be required to keep pace with the rapidly developing area of AI. This is particularly true for post-market activity as AI solutions are often designed to learn and evolve through use.

Conclusion

MTAA commends the Australian Government on the request for input on how to mandate guardrails on those developing and deploying AI in Australia in high-risk settings. While much work remains to support the ever-increasing adoption of AI in Australia, it is encouraging to see the commitment of government to address the use of AI in high-risk settings.

MTAA and our member companies look forward to the continued collaboration and engagement on AI related issues and practices. We welcome further discussions with the Department of Industry, Science and Resources as they become available and encourage the review of our more detailed response to the *TGA Consultation - Clarifying and strengthening the regulation of Artificial Intelligence (AI)* to be submitted 13 October 2024.