Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

Supporting responsible AI: discussion paper

Medical Technology Association of Australia
in collaboration with
The Asia Pacific Medical Technology Association
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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.

Asia Pacific Medical Technology Association

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific. As a trade association, our mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.

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Executive Summary

MTAA welcomes the opportunity to comment on the *Safe and Responsible AI in Australia* discussion 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. In order to provide a regional perspective of AI in MedTech, MTAA has welcomed the input of APACMed into this response to the discussion paper.

The Department of Industry, Science and Resources has recognised the opportunity to place Australia as world leader in the responsible use of AI. AI is poised to offer advantages across all sectors of the economy, and to public and private organisations of all sizes. MTAA appreciates the chance to provide input on the specific AI aspects that affect the healthcare sector and MedTech industry.

As recognised in the recently released MTAA digital health report "Digital Health: Breaking Barriers to Deliver Better Patient Outcomes" current applications of AI/ML in healthcare including clinical decision-making, remote monitoring, and robotic surgical procedures are seeing substantial growth. AI/ML were identified as part of the anticipated regulatory applications via the Therapeutic Goods Administration (TGA) over the next five years for 45% of the MTAA Digital Health survey respondents.

The use of AI and ML in healthcare poses new regulatory challenges and there is need for regulation to evolve to address sector risk. MTAA believe that the existing medical device regulators such as the TGA are best placed to incorporate emerging AI/ML regulation within their existing medical device assessment frameworks.

AI/ML is not new to healthcare with many medical devices already utilising technologies approved by TGA. Existing TGA medical device regulatory requirements are technology-agnostic for software-based medical devices and apply when incorporating components like AI/ML as part of the *Therapeutic Good Act 1989*.

Because of the unique, complex, and highly regulated nature of medical technology, any broad regulation of AI, even regulation of AI aimed at the medical industry generally, could have unintended consequences for patient outcomes and the medical technology industry. It is important that substantial consultation with the medical technology industry occurs regarding any proposed regulation.

The responses and comments provided within this document are an amalgamation of comments from some of the 110 MTAA member companies, in particular members of the digital health related groups: the MTAA Digital Health Advisory Group and Cyber Security Working Group. From a regional perspective, responses and comments were provided by APACMed members who are part of the Regulatory Digital Working Group.

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General Comments

AI/ML tools can help empower and leverage diverse healthcare data to build state-of-the-art decision support interventions (DSI) and diagnostics. AI/ML services can also support: the extraction of valuable insights on product safety and effectiveness from clinical notes; drug discovery by identifying insights that might have otherwise been overlooked; and a deeper understanding of data throughout the product lifecycle for patients, providers, manufacturers, scientists, and regulators.

MTAA recommends requirements for clear identification and disclaimers for users when interacting with AI where it may be assumed that the interaction is with humans. In particular, within social media settings where the vulnerable, including very young, may be unable to recognise the use of AI rather than human actors.

Regional APACMed Comments

The discussion paper should further consider how government can influence, manage, or control prompt engineering in AI. As ML develops, currently accepted queries provide access to information that may be used to cause harm. Identifying the context and legitimacy of the user is vital to allow access to information for educational and research purposes rather than to cause harm.

The discussion paper does not have a clear focus on addressing the multi-factored risks from AI-generated deep fakes and the threat posed by rapid incremental growth in these capabilities when in the hands of both adversary state and non-state actors. This threat will impact the ability of citizens, governments, and organisations to source credible and reliable information.

The trajectory of AI tech and lack of supportive, risk-mitigating technology and regulatory control or oversight could lead to a position of being unable to attribute credibility to intelligence or news streams or attain access to critical information reliably. The real-world impacts on intelligence analysis, proactive risk mitigation and incident/crisis management for the private and public sectors could be significant.

Definitions

Do you agree with the definitions in this discussion paper? If not, what definitions do you prefer and why?

It is important to recognise that AI and related technologies may be viewed and defined from numerous disparate positions from users, developers and designers to decision makers and regulators. The definitions adopted by Australia should align with internationally recognised and adopted definitions.

MTAA is primarily focused on medical devices regulated by the Therapeutic Goods Administration (TGA) and default to definitions within the Therapeutic Goods regulations (*Therapeutic Goods (Medical Devices) Regulations 2002)*. However, the highly publicised AI text-based products like ChatGPT, GPT-4, Bard, and other large language models (LLMs) have potential to affect Australians across all industries including healthcare.

MTAA suggests the addition of a definition for Deep Learning (DL), which includes neural networks, as a subset of Machine Learning (ML). Existing frameworks differentiate between the three definitions (AI vs. ML vs. DL) and recognition of these differences within the definitions adopted by Australia is recommended.

Regional APACMed Comments

The AI definition misses Generative Adversarial Networks (GANs) created AI systems with machine-defined objectives. Most AI systems involve some level of human coding.

Potential gaps in approaches

Potential risks

What potential risks from AI are not covered by Australia's existing regulatory approaches? Do you have suggestions for possible regulatory action to mitigate these risks?

While safe and responsible use of AI is the goal, there is a risk that AI is either over-regulated or inconsistently regulated in Australia compared to other jurisdictions. This may restrict the level of use, investment, and development of AI/ML incorporating solutions within Australia.

Access to AI as an ethical principle needs consideration, with the growing "Digital Divide" for digital health utilities, inequalities in access to AI for disadvantaged, rural and remote Australians will have socioeconomic impacts that will need to be addressed.

Principal concerns include:

- Data breaches during collection, storage, or transmission of private patient data to enable an analysis of results or to enable model and algorithm development.
- Biased algorithms due to inadequate access to large volumes of data or access to impoverish data due to condition or population constraints.
- Potential harm due to faulty algorithms making inaccurate diagnoses that negatively impact patient management or treatment.
- Liability risk due to reliance on or use of faulty algorithm recommendations or the provision of erroneous results that lead to inadequate clinical decisions.
- Therapeutic impact from the loss of human interaction in care delivery and the doctor-patient relationship.
- Ethical concerns as patient data may be used in unethical ways or without patient approval, including commercial use.

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Because of the unique, complex, and highly regulated nature of medical technology, any broad regulation of AI, even regulation of AI aimed at the medical industry generally, could have unintended consequences for patient outcomes and the medical technology industry. It is important that substantial consultation with the medical technology industry occurs regarding any proposed regulation.

Non-regulatory initiatives

Are there any further non-regulatory initiatives the Australian Government could implement to support responsible AI practices in Australia? Please describe these and their benefits or impacts.

Initiatives and incentives which encourage gold standard use of AI in the form of frameworks and guidelines play an important part of AI governance without hampering innovation and growth.

Coordination of AI governance

Do you have suggestions on coordination of AI governance across government? Please outline the goals that any coordination mechanisms could achieve and how they could influence the development and uptake of AI in Australia.

AI has the potential to affect all Australians and industries. A national approach is encouraged to ensure the reach of governance across all sectors. However, industries such as healthcare bring a unique set of challenges that need individual and specialist attention when dealing with potentially life and death decisions. Regulators and decision-makers such as the TGA and ADHA need to play a core role in the development of any national strategy.

Responses suitable for Australia

Governance measures by other countries

Are there any governance measures being taken or considered by other countries (including any not discussed in this paper) that are relevant, adaptable and desirable for Australia?

The White House guidance for the regulation of AI applications establishes a framework that may be built upon or referenced when developing Australian rules and regulation. The U.S. Food and Drug Administration (FDA) issued the "*Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*" which outlines five actions the FDA intends to take in regard to AI/ML.

Regional APACMed Comments

Australia should consider including South Korea and/or Japan as reference, given Korean MFDS has been one of the leading regulatory authorities in Asia to issue regulation & guidance on AI/ML.
The European AI Liability Directive will likely not be adopted as the legislators have come to the realisation that the update of the product liability directive in conjunction with the AI Act

provisions are better suited to protect affected persons. On a horizontal level China has a three-year roadmap and thirty draft rules for recommender systems.
Also, the China Medical Device Standardization Association (CMDSA), a subordinate unit of the National Medical Products Administration (NMPA), issues standards that have a legal status, of which various standards have AI-specific aspects.

There is a lack of legally binding provisions as applicable to foundation models. It is also difficult for SMEs to contractually impose obligations on big tech providers of large language models so they can build these into their products in a way that complies with sectoral legislation, such as medical device regulation. The Commonwealth should consider imposing mandatory requirements on foundation models to facilitate innovation including in the medical device sector.

Consultation with medical device manufacturers and sponsors is strongly recommended to ensure that Australian regulations for AI medical devices align with the comparable overseas regulators who are more advanced in this space such as the US FDA. In addition, it is imperative that education and training is provided by the TGA in this space to ensure sponsors and manufacturers are kept abreast of the rapid development in any medical device AI/SaMD related regulatory reforms (Inc. software apps.)

Target areas

Public and private sector approaches

Should different approaches apply to public and private sector use of AI technologies? If so, how should the approaches differ?

A one size fits all approach may not be suitable for all sectors be they public or private. Certain sectors and technologies will require distinct considerations such as healthcare/MedTech where specific consideration and consultation should be provided due to the potential consequences.

Australian Government support

How can the Australian Government further support responsible AI practices in its own agencies?

The development and adherence to a federal framework would support responsible AI practices within government agencies.

Generic solutions

In what circumstances are generic solutions to the risks of AI most valuable? And in what circumstances are technology-specific solutions better? Please provide some examples.

At a national level generic solutions are preferable, however, specific solutions for certain technologies and industries such as healthcare/MedTech will be required.

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Transparency

Given the importance of transparency across the AI lifecycle, please share your thoughts on:

a. where and when transparency will be most critical and valuable to mitigate potential AI risks and to improve public trust and confidence in AI?

b. mandating transparency requirements across the private and public sectors, including how these requirements could be implemented

Because of the unique, complex and highly regulated nature of medical technology, any broad transparency requirements of AI, even if aimed at the medical industry generally, could have unintended consequences for patient outcomes and the medical technology industry. It is important that substantial consultation with the medical technology industry occurs regarding any proposed requirements.

a. high-risk AI applications

Do you have suggestions for:

a. whether any high-risk AI applications or technologies should be banned completely?

Applications that allow the identification or impersonation of others such as facial recognition and deep fakes need careful consideration for each specific technology and use case.

Many high-risk AI applications are beneficial and are already extensively used, Clinical Decision Support (CDS) is an example of Automated Decision Making (ADM) which is used with great success in the healthcare industry. Good examples of this are within Radiology and Pathology, where AI/ML is used to detect complex patterns and allows clinicians to make informed decisions.

b. AI applications that should be banned

b. criteria or requirements to identify AI applications or technologies that should be banned, and in which contexts?

Due to the unique, complex and highly regulated nature of medical technology, any broad prohibition of AI applications or technologies, even if aimed at the medical industry generally, could have unintended consequences for patient outcomes and the medical technology industry. It is important that substantial consultation with the medical technology industry occurs regarding any proposed ban.

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Public trust

What initiatives or government action can increase public trust in AI deployment to encourage more people to use AI?

Public trust may be increased through the observation of adequate regulation ensuring the safe and responsible use of AI. Focusing on the potential benefits AI offers to industries such as healthcare, AI can empower the leverage of diverse healthcare data to build state-of-the-art decision support interventions (DSI) and diagnostics. AI/ML services can also support: the extraction of valuable insights on product safety and effectiveness from clinical notes; drug discovery by identifying insights that might have otherwise been overlooked; and a deeper understanding of data throughout the product lifecycle for patients, providers, manufacturers, scientists, and regulators.

Implications and infrastructure

Banning high-risk activities

How would banning high-risk activities (like social scoring or facial recognition technology in certain circumstances) impact Australia's tech sector and our trade and exports with other countries?

Bans, particularly where Inconsistent with other jurisdictions, could prevent important medical technologies from being developed and/or implemented in Australia, to the detriment of patients and the healthcare industry.

Risk-based approaches

Risk-based approach

Do you support a risk-based approach for addressing potential AI risks? If not, is there a better approach?

MTAA supports a risk-based approach to AI/ML oversight that targets factors most likely to negatively affect patient outcomes in high-risk use cases. These high-risk uses include leveraging AI/ML technology to make final decisions affecting medical diagnosis and treatment without human intervention. Lower risk use cases could include applications to support the documentation of care for review by the clinician. Recognising that healthcare applications are heterogenous, a focus on high-risk use cases helps to ensure that potential harms are addressed without stifling innovation or impeding access to benefits from low-risk uses of AI/ML.

Regional APACMed Comments

A risk-based approach is preferable, however the table in Box 4 is not comprehensive enough in its current state given the potential power of AI and the speed of development. Further, unless for simplistic, low-risk tasks, the default should be for humans to make final decisions using the research and decision-making suggestions of AI, as opposed to allowing AI to execute without

human involvement. Again, this concern relates not so much on where AI is today, but where AI will be in the future, and in seeking efficiencies, we have the potential to lose control.

Benefits or limitations of a risk-based approach

What do you see as the main benefits or limitations of a risk-based approach? How can any limitations be overcome?

With any approach the adoption of standards is essential. MTAA encourages regulators to align with international standards—many of which are currently in development—to provide consistency, clarity, and thoroughness to support the effective and safe use of clinical machine learning products throughout the AI/ML lifecycle.

The 'Application of AI Technologies in Health Informatics' ISO/TC 215 AHG2 – Final Report Published in 2021, provides a potential roadmap to future directions in developing standards for AI health applications. While healthcare specific, this report provides information relevant to AI standards across industries and regulatory agencies.

Risk-based approach by sector

Is a risk-based approach better suited to some sectors, AI applications or organisations than others based on organisation size, AI maturity and resources?

The healthcare sector is well suited to a risk-based approach because of the wide range of uses and risk profiles, combined with having existing approval mechanisms such as the TGA. Risk profiles vary from low-risk administrative task to high-risk leveraging of AI/ML technology in clinical decisions support (CDS) affecting medical diagnosis and treatment, both with or without human intervention.

Risk-based approach – attachment C

What elements should be in a risk-based approach for addressing potential AI risks? Do you support the elements presented in Attachment C?
Attachment C is found on page 40 of the discussion paper.

As described in Attachment C, especially for higher-risk use cases, human expert oversight over AI/ML systems can help maintain safety and accuracy and provide continuous improvements to retrain models as needed. In determining the role of human review, regulators should assess the intended application, capabilities, and limitations of AI/ML systems. This analysis should consider the probabilistic nature of AI/ML, confidence levels, latency of the system, and how best to incorporate human input into the overall operation of the system, if applicable. Human users should be appropriately trained on real-world scenarios and have ways to exercise meaningful oversight.

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Regional APACMed Comments

The association between surgical robots and the need for the final decision to be made by humans overlooks research that suggests, in some use cases, the human must be taken out of the loop. Today, surgery to treat certain eye diseases is impossible to do by humans or humans operating a surgical robot. Only fully autonomous robots have the computing capacity to monitor +100 parameters and make split-second decisions and translate these into movements of the surgical instruments. It would therefore be unwise to block such applications from the Australian market simply on the basis that humans cannot intervene in the final decision.
To decide whether the human should be the decision-maker or not, the performance and safety of the human alone, the human-AI team and the AI alone should be compared. While usually the human-AI team will outperform the AI alone, there are increasingly cases where the AI outperforms the human-AI team.

The European Parliament adapted the AI Act accordingly by rephrasing this as: Art. 14(e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a "stop" button or a similar procedure that allows the system to come to a halt in a safe state, except if the human interference increases the risks or would negatively impact the performance in consideration of generally acknowledged state-of-the-art.

Existing assessment frameworks

How can an AI risk-based approach be incorporated into existing assessment frameworks (like privacy) or risk management processes to streamline and reduce potential duplication?

It is essential that AI is considered within or in conjunction with existing frameworks to complement existing agency policies and standards. A notable example is the NSW Artificial Intelligence Assurance Framework which assists agencies to design, build and use AI-enabled products and solutions.

LLMs or MFMs

How might a risk-based approach apply to general purpose AI systems, such as large language models (LLMs) or multimodal foundation models (MFMs)?

A risk-based approach should be flexible and encompassing enough to cover existing models and potential future models.

Voluntary or self-regulation

Should a risk-based approach for responsible AI be a voluntary or self-regulation tool or be mandated through regulation? And should it apply to:

a. public or private organisations or both?
b. developers or deployers or both?

The enforcement of a risk-based approach may differ depending on the industry and individual actor. In relation to medical technology, whether a risk-based approach should be used on a voluntary/self-regulation or mandatory basis is dependent on a number of factors including the extent of international

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and domestic product approvals. MTAA encourages governance (in particular within the MedTech industry) without hampering innovation and growth.

Conclusion

MTAA and APACMed commends the Australian Government on the request for input on how to mitigate any potential risks of AI and support safe and responsible AI practices. 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 risks and alleviate public concern.

Both MTAA and APACMed 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.