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SUBMISSION

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AMA submission to the Therapeutic Goods Administration consultation on clarifying and strengthening the regulation of Artificial Intelligence (AI)

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Introduction

The Australian Medical Association (AMA) welcomes ongoing consultation with the Therapeutic Goods Administration (TGA) regarding a review of therapeutic goods legislation for the safe and responsible use of Artificial Intelligence (AI) in Australia.

The AMA notes the broader government activities occurring across national, state and territory governments towards establishing a consistent regulatory framework for the application of AI across industry settings. This is an important step in responding to the many opportunities and attendant risks presented by AI across industries.

The TGA carries responsibility to adapt current regulatory frameworks for medical devices to accommodate new technologies using AI, without compromising patient outcomes. This consultation compliments the Department of Health and Aged Care's Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review, and the Department of Industry, Science and Resources' (DISR) proposed mandatory guardrails for safe and responsible AI.

In our feedback to the DISR's consultation, the AMA voiced approval for the *Option 2 Framework approach.* This whole-of-government approach best supports proactive, industry-specific regulation of AI to establish pre-market safeguards and risk mitigation measures that operate to construct a cohesive regulatory environment in Australia.

The proposed national approach to regulating AI engages technology developers and users (deployers), the primary drivers of AI innovation, in the centre of the government strategy. As the regulatory body for medical devices and therapeutic goods, the TGA is instrumental to implementing direct oversight of AI products in healthcare, aligned with cross-jurisdictional standards.

The AMA has previously stated that reliance on technology innovators' self-regulation poses an unacceptable risk to consumers and medical professionals. Progress in the AI space will be largely driven by free market, profit-driven entities and these must be subject to strict accountability and clear parameters for the ethical and safe use of AI in healthcare.

Among the AMA's principles for implementing effective regulation of AI, the following must be supported through governance of medical devices:

- clearly established responsibility and accountability for any errors in diagnosis and treatment caused by AI products
- stringent data governance and security measures for data collected and used by AI applications, protecting the privacy and security of patient health information
- visibility of AI generated components of care and advice, treatment or diagnostic procedure to be undertaken
- information which supports clinical decision making is substantiated at any point in time
- use of health data in medical devices using AI requires full disclosure and patient consent
- data undergirding machine learning algorithms for AI in healthcare is inclusive and representative to mitigate against bias.

The AMA supports the TGA's approach to regulating AI products that fit the definition of a medical device under the *Therapeutic Goods Act 1989*. TGA regulation is risk-based and proportional. AI technologies are subjected to TGA regulation when they are used for diagnosis, treatment, or monitoring of health conditions, including tools like chatbots and mobile apps.

Existing TGA classification rules have provided a sound basis for managing innovation in medical devices. However, the nature of AI requires broader regulation, adaptable to rapid change. Many software devices will incorporate AI components over time. The AMA reiterates the exclusion of certain software from regulation requires re-evaluation due to increasing complexity. Data, the power source of the AI ecosystem, crosses jurisdictions and contributes to system complexity. Contributing to data governance should also be of central concern in the regulation of AI-using software as a medical device (SaMD).

The AMA is pleased the TGA is responding to stakeholder feedback and seeking alignment with international regulations to AI. The AMA has confidence in the TGA's robust systems, which require medical devices to provide clinical and technical evidence for the device's safety and effectiveness. Stricter requirements are imposed upon higher-risk products. We support leveraging this effective regulatory mechanism to support responsible deployment of AI within medical practice.

1. Risk and principles-based framework

The AMA has consistently advocated for a risk-based approach to the implementation of AI. We are pleased to see this approach is being consulted and incorporated into a national regulatory framework that will build trust and confidence in the rapidly evolving digital health solutions using AI. The DISR's proposed method to defining high-risk AI based on principles is appropriate to support a responsive regulatory framework in healthcare, capable of supporting interoperability, while adapting to technological advancements.

Regulating the application of AI in healthcare requires a tailored approach that allows for the adoption and integration of safe technologies while protecting practitioner and patient safety. The application of AI in healthcare must always be considered high-risk, primarily due to potential negative consequences that could arise from systemic errors, patient privacy issues, and algorithmic biases. AI associated errors can lead to significant harm, such as misdiagnosis or inappropriate treatment, with potentially irreversible impacts on patient health.

Healthcare requires a bespoke AI regulatory framework, integrated with existing regulation of therapeutic goods and medical practice, facilitated and assisted by the establishment of a clinical governing body. Ongoing collaboration with experts in AI, healthcare, ethics, and law is critical to developing effective regulations that adapt to the evolving landscape of AI technology.

The AMA supports the TGA's classification for medical devices based on risk, a system that works effectively to promote clinician and patient safety in healthcare. The AMA approves of the TGA's intent to align the legislative and regulatory framework for therapeutic goods with the intent of the DISR's proposed mandatory guardrails for AI.

2. Potential changes to the *Therapeutic Goods Act*

Language and Definitions

A review of the language and definitions in the *Therapeutic Goods Act* is necessary to clarify regulatory responsibility for products applying AI for therapeutic uses. As machine learning drives AI capabilities, AI's clinical scope will increase. Engineered, automated systems and functions must be defined and transparent to enable appropriate regulation based upon a risk-based assessment of use in the healthcare space.

The AMA agrees the TGA's cited terms "supply", "manufacture" and "sponsor" are integral to the structured regulation of therapeutic goods. Because technology is ubiquitous, software using AI will become increasingly accessible and the scope of its use will expand. The definition of supply of therapeutic goods must capture AI tools, including general purpose AI (GPAI), that are, or could be applied to healthcare and clinical practice.

From a regulatory standpoint, it is crucial to clarify who is responsible for the outputs of AI systems and guarantee legal liability for current and emerging AI tools. Without clear definitions, breaches of the *TGA Act* cannot be attributed to the appropriate party in each instance of use.

A review of definitions and language regarding legal responsibilities and appropriate legal entities should be aligned with terminology and concepts in related legal instruments across the regulatory landscape. These include the amended *Privacy Act*, cybersecurity legislation, and the risk-based regulatory framework under development by the DISR to support AI adoption across industries.

Legislated language must adequately communicate and account for activities now likely to be performed by AI, to facilitate full disclosure of AI-generated health information, advice, treatment, or diagnostic procedure to be undertaken.

Definitions should align with international terminology for consistency in future changes to regulation. The AMA agrees with recommendations from healthcare technology groups to provide a definition for Deep Learning (DL). DL encompasses neural networks as a subset of Machine Learning (ML). Current frameworks distinguish between AI, ML, and DL. It is advised that Australia acknowledges these distinctions in its definitions.

3. Potential changes to medical device regulation

As the regulatory body for medical devices, the TGA provides a proven and highly effective role in promoting clinical safety with the use of technology in healthcare. Medical practitioners trust determinations on safety and efficacy made by the TGA. The TGA already regulates some AI as

medical software, but not all. The AMA believes the scope of regulated AI-using SaMD needs to expand to ensure AI products used in healthcare — whether captured within "health software" or "health software products" — are regulated according to the degree of risk associated with their function and monitored closely in the case of low-risk exemptions to prevent bracket creep.

Not all AI will require prospective analysis and assessment, but all AI that fits under the TGA's regulatory scope must actively participate in monitoring to guarantee safety standards and be subject to post-market review. For example, should AI scribes come under TGA regulation, we would expect that acknowledging compliance with basic standards as outlined by an appropriate order would suffice prior to entering the market, whereas AI tools directly involved in diagnostics would require some pre-assessment. There would need to be resourcing considerations to ensure this does not impede existing regulatory roles.

4. Classification rules

Healthcare tools using AI are not perfect and will continue to break the bounds of their current scope of classification. It is within the nature of technology to perpetually outpace regulation. Regulation of medical devices using AI must be flexible and responsive to these changes.

The AMA supports amendments to the current classification rules 4.5(1) and 4.5(2) to capture medical devices being used to predict clinical outcomes or provide prognostic information. Medical devices such as these will invariably influence and inform clinician treatment plans. The attendant risk to patients demands regulatory protections provided at a higher classification, determined by the seriousness of the disease or condition in question and whether the information is being provided to a clinician or a consumer.

Specific classification for AI

There is still significant risk of harm associated with devices intended to provide therapy through the provision of information. Depending on the intended purpose of the software, these devices may be Class I or higher in Australia.

If captured within the current regulatory framework for SaMD, the AMA considers many AI applications require a higher classification than this provides. We recommend specific classification be developed for devices that are, or incorporate, AI systems or models.

The TGA has appropriate regulatory structures in place to support the recommended tiered, application-based approach for governing the use of AI. Currently, the intended purpose of a healthcare device determines the classification and the attendant requirements imposed on that device. If a medical device is driven, or influenced by, an item of software, the software has the same classification as the medical device. This is sufficient for most medical devices. However, in the case of software using AI, consideration must also be given to the processes inherent in the function, which carry equally significant risks, usually associated with data.

There is an argument to be made that any AI software collecting, using and storing patient health data must be subject to data governance and the highest standards of cybersecurity. The AMA notes the TGA has updated its regulatory position regarding data collection components used by SaMD in smart devices, tablets, laptops, and similar digital hardware. However, the surest means of regulating this

health data is to capture these applications within an expanded definition of an "accessory to a medical device".

Classification criteria for AI

The TGA could consider classifying healthcare devices using AI by two major risk criteria: intended purpose and "inherent processes". Inherent processes refer to the means of its function and the risk they pose, such as data use and management, and whether the device operates on a foundation model supplied by a third-party technology provider. This approach needs to capture devices using large language models (LLMs) and other GPAI used in healthcare that collect, store and use patient data. These applications must be subject to device regulation that complements other regulatory instruments like the *Privacy Act* and newly instated cybersecurity laws.

Brought within the medical device framework, lower classifications for some healthcare devices using AI may not be sufficient to mitigate risks to users. The AMA recommends classification of software-based healthcare tools, differentiated by the intended user (practitioners or consumers), must be balanced carefully.

Under the current arrangements, the software intended for use by a relevant healthcare professional is typically a lower classification than if it was intended to be used by an individual. The health practitioner is equipped to demonstrate clinical judgement in the use of an AI tool. The TGA has acknowledged in most cases this will result in such software being a lower classification than what it might be in other jurisdictions, such as the European Union. Where software is intended for use by a healthcare professional, the current lower classifications may not suffice for the risks inherent in AI processes, which should largely be associated to software manufacturers and sponsors.

Where software is intended for use by an individual, the tool should similarly be captured in the TGA's framework and be subject to equal classification based on risk to the consumer, who does not benefit from clinical expertise to filter or judge the reliability of its outputs. Health information from software devices can generate unnecessary fear and anxiety about a condition, or conversely lead to a scenario where a patient is not concerned enough. Regulation should account for these risks by providing a risk-averse classification that encourages consumers to seek practitioner input when required.

5. The essential principles

The AMA supports the requirements in essential principle 12.1, requiring programmed or programmable medical devices, or software classified as a medical device, to be designed and produced to ensure safety, performance and reliability for intended use. This principle provides a sound foundation towards ensuring patient safety, data integrity, and compliance with state-of-the-art practices for AI products.

1. **Performance standards**: The device must ensure safety, accuracy, usability, and reliability, while facilitating updates and disclosing known vulnerabilities.
2. **Data management**: Data affecting device performance must be representative, high-quality, maintained for integrity, and managed to reduce bias and risks.
3. **Resilience**: The device should be resilient to interactions that could compromise safety, providing timely warnings and verification of correct operation.

4. **Development practices**: It should be developed following best practices in design, security, risk management, and quality control.
5. **Compatibility**: When used with computing platforms, the device must consider the platforms' capabilities and external IT environments.
6. **User instructions**: Manufacturers must provide clear instructions on operational requirements, including hardware and security measures.
7. **Cybersecurity**: Devices must incorporate robust cybersecurity measures to prevent unauthorised access and address known vulnerabilities effectively.

The essential principles need to be maintained and adapted as the scope and complexity of AI expands. They should require products to clearly disclose AI operations and when AI is responsible for generating outputs in a medical device. If medical practitioners are not informed of AI-generated outputs they cannot be expected to evaluate and judge the material. It is essential to the clinical process that practitioners critically review all AI-generated information or advice.

The AMA supports the TGA's essential principles in requiring manufacturers and suppliers to identify AI functions within products used in healthcare:

- 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.

The AMA approves of the TGA's evidence requirements for software using AI and emphasises these must be updated as AI evolves. Wherever possible, AI applications should disclose how calculations have been arrived at. The 'black box' effect must be minimised so far as possible to build transparency and trust in the machinery of AI systems. Maintaining high safety and transparency standards requires the highest degree of scientific, clinical, and engineering evidence for clinical AI products.

Manufacturers of medical devices using AI must therefore be subject to robust standards for quality management systems for generating, collating, assessing and maintaining evidence in conformity with the essential principles for safety and performance.

Software exclusions

The increasing complexity of software used in health and wellness applications is moving these devices from a general information functionality towards incorporating diagnostic tools. Regulation must be flexible to respond to AI applications that begin as general-purpose tools and end as therapeutic goods.

The TGA consulted regarding the regulation of SaMD under the *TGA Act* in 2020. At this time there was some disagreement between the TGA and stakeholder submissions regarding the scope of SaMD, as a subset of health software. The TGA's limited definition decreases the field of regulation for software considerably.

The definition of "medical device" is crucial for ensuring the efficacy and safety of these products. We caution against the use of exclusion power in the *TGA Act* for SaMDs, and we oppose any broad exclusions for software that meets this definition.

The AMA contends that even low-risk software can pose patient harm. The scope of regulation should be broadened to ensure AI applications used in clinical contexts are captured under the medical device framework. An adjustment to the classification rules for medical devices goes some way in this regard. However, the AMA remains concerned many general-purpose AI tools pose significant risk to healthcare.

We would support the TGA amending regulation to ensure all software intended for use in healthcare, whether general purpose or administrative tools not considered clinical support software, are subject to software manufacturer compliance with the essential principles. All AI used in healthcare should be subject to classification based upon the level of risk posed by their purpose and their internal function. The TGA should conduct post-market monitoring on all software devices using AI in the clinical context as a mechanism to imposing quality and safety standards.

Exemptions

The AMA agrees that exempting certain medical devices allows for a streamlined regulatory process for sponsors, which is important to support continued innovation of AI products. However, devices not deemed to be clinical decision support software can change in function over time. Exemptions due to low-risk application or regulatory overlap must be assessed on a case-by-case basis and monitored to determine where changes are needed to address regulatory gaps.

Because the regulatory landscape for AI stretches across multiple legal instruments, including consumer, data protection, competition, copyright and anti-discrimination law, TGA regulation must address gaps for AI tools used in healthcare. While some exemptions may be considered, especially where alternative frameworks like the NPAAC exist, these must be carefully assessed to ensure they don't lower safety standards.

Even if an alternative framework sets accreditation standards equal to or more stringent than TGA regulatory processes, contingencies should be built into any conditional exemptions to ensure that if, later, the alternative accreditation or regulatory framework is weakened or removed, full TGA regulation automatically resumes. TGA post-market action against products that fail to meet safety, quality, and performance standards must be swift in responding to reported adverse events.

The AMA calls for clarity on how the TGA will monitor exemptions to specific AI tools and emphasises the need for ongoing regulation to ensure patient safety. An AI health advisory body could support the TGA in facilitating ongoing consultation with stakeholders to monitor gaps and inform regulatory decisions.

6. International harmonisation

International regulators have advanced further than Australia in managing emerging technologies using AI. The government must seek alignment with international standards to ensure Australian requirements do not inhibit growth and innovation in the technology sector, nor expose our digital systems to risk. This is particularly important regarding management of databases undergirding AI

capabilities. The AMA strongly encourages the government to consult widely with medical device manufacturers and sponsors to strike this balance.

7. Transparency

Regulatory safeguards must require developers to be transparent regarding AI design and ensure AI application adheres to agreed ethical principles. The September 2023 guidance issued by the TGA emphasised that those who develop software that constitutes a medical device must "understand and demonstrate the sources and quality of text inputs used to train and test the model, and in clinical studies, in addition to showing how the data is relevant and appropriate for use on Australian populations".

This issue of quality and transparency relates to the datasets undergirding AI systems deployed in healthcare. A regulatory gap regarding foundation models has been raised by stakeholders in this consultation. Trained on extensive datasets often drawn from the internet, these large-scale machine learning models constitute the foundational, versatile building blocks in AI, facilitating the development of a range of applications across different industries.

Foundation models are general, performing multiple tasks without task-specific training. They are transferable, adapted or fine-tuned for specific applications or domains. And they are scalable, trained on vast data and computational resources to learn complex patterns. The AMA is concerned:

- The vast training datasets are difficult to review, complicating consent, copyright, personal data protection, and liability.
- These models consolidate the power of big tech and raise competition issues. Few technology firms can meet the high computational demands, which means model ownership is concentrated in the hands of large corporate entities.
- The general-purpose nature of these models complicates the allocation of risks and liabilities between end users, foundation model owners and software developers using the foundation models.

Developers, who have control over the datasets and stand to gain financially, may face challenges in being held accountable for unforeseen uses and risks. Meanwhile, those deploying foundation models have specific context knowledge but might struggle to address issues without access to the underlying code and data, complicating the ability to audit or rectify problems.

Foundation models, such as OpenAI's GPT-4 and Google's LaMDA, have gained prominence with the rise of generative AI applications like ChatGPT and Bard. These models are owned and employed across national jurisdictions around the world.

The regulation of foundation models was one of the most contentious issues in the European Union's *Artificial Intelligence (AI) Act*, creating significant debate. The TGA must consider how Australia's regulatory framework can provide transparency regarding AI applications with software based upon foundation models and ensure liability is apportioned to big tech owners. GPAI model providers should be required to create and publish a detailed summary of the data used in the training of their foundational modelling.

Software used in healthcare interacts between sensitive patient data, complex clinical determinations, medical prescriptions and routine generation of private information as a matter of course. This will

increasingly include digital tools using AI that are not deemed medical devices under the current regulations. General-purpose AI systems that do not pose systemic risks should nevertheless be subject to specific transparency standards. Providers of these AI models must be required to maintain up-to-date technical documentation and make it accessible to downstream AI system providers.

Contact

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Other points

For more information regarding AMA's recommendations around AI, see the AMA Position Statement Artificial Intelligence in Healthcare.

For more detail on the AMA's advice around ADM, see the AMA Submission to Automated Decision Making and AI Regulation (2022).

For more detail on the AMA's advice regarding national regulation of AI, see the AMA Submission to the DISR proposed mandatory guardrails (2024).

See AMA Position Statement on Data Governance and Patient Privacy and AMA Position Statement System Interoperability in Healthcare.