Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Report: Clarifying and strengthening the regulation of Medical Device Software including Artificial Intelligence (AI)

Outcomes from the review of therapeutic goods legislation, regulation and guidance

Version 1.0, July 2025

Acknowledgments

The TGA would like to thank everyone who contributed their time and effort to the review, whether through participation in online webinar consultations or making a formal submission to the public consultation. Stakeholder input throughout the review process has provided crucial feedback on the existing framework and insights into the use of AI models and systems, allowing us to identify aspects of our framework where refinements will be needed to further strengthen our framework to support the increasing use of AI.

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Executive summary

In the 2024-25 federal Budget, the Australian Government provided $39.9 million over 5 years for the development of policy and capability across government to support Safe and Responsible AI. The measure includes work to clarify and strengthen existing laws and address risks and harms from Artificial Intelligence (AI) through an immediate review of priority areas, including health and aged care sector regulation, Australian consumer law, and copyright law.

As part of the Australian Government's Department of Health, Disability and Ageing (the Department), the Therapeutic Goods Administration (TGA) regulates therapeutic goods, including software and AI models and systems when they meet the definition of a medical device under the *Therapeutic Goods Act 1989*. Software-based medical devices (including AI models and systems) have been regulated by the TGA for many years.

In 2021, we clarified the classification levels of software to account for the potential and emerging risks of harm associated with software, and introduced a number of "carve-outs" for very low risk products or products that had oversight from other regulators. With input from relevant industry stakeholders, we published guidance about our refined regulatory framework, setting out how regulatory requirements apply to these kinds of devices. Since that time, the TGA has monitored the refinements to identify when further review and adjustment was required, including to address emerging risks as technology like AI is rapidly adopted and deployed in healthcare settings.

In 2024, the TGA conducted a review in tandem with the Department's broader review of health and aged care legislation, to:

- determine whether our existing legislation, regulations and guidance are appropriate to meet the challenges associated with an increasing use of medical software and AI across the healthcare sector, and
- identify measures to clarify and strengthen existing regulation to mitigate risks and leverage opportunities associated with medical software and AI use in the therapeutic goods sector.

Extensive targeted engagement with stakeholders from cohorts including the medical device industry, consumers and clinicians has been conducted, followed by a public consultation process seeking more information and feedback about strengths of the system, opportunities for improvements and identified issues and areas of concern. Our review also included mapping the existing medical device legislative framework against the mandatory guardrails for use in high-risk settings proposed by the Department of Industry, Science and Resources (DISR) in their consultation: *Introducing mandatory guardrails for AI in high-risk settings: proposals paper*.

Findings from our review should be considered within the context of the TGA's ongoing work, identifying areas for priority reform to ensure the regulation of all medical devices remains fit for purpose, including AI models and systems that meet the definition of a medical device. While our findings indicate our existing legislative framework is largely appropriate for the increasing use of AI in therapeutic goods, we recognise AI use is rapidly increasing in all sectors, and regulatory approaches to AI are continuing to develop around the world.

The TGA will continue to engage with regulators in other jurisdictions and work closely with relevant stakeholders to ensure regulation remains appropriate and resources are developed to support developers, sponsors and manufacturers to meet their regulatory obligations. While work continues on whole-of-economy issues and approaches under the Australian Government's Safe and Responsible AI Budget measure, the TGA will continue to regulate using a technology-agnostic approach based on risks and principles to provide timely and effective regulation of emerging technologies, including innovative software products incorporating AI.

Following our review, we propose to undertake further targeted consultations on a number of regulatory refinements and compliance activities during 2025 and 2026. These consultations are required to supplement our collaboration with other Portfolio agencies and the work conducted across the economy in support of the Safe and Responsible AI Budget measure.

1. Findings

The TGA regulates software, including AI models and systems, when they meet the legislative definition of a medical device,[1] software used to manage clinical trials, and software for design and manufacture of therapeutic goods. Although the focus of this report is medical devices, many of the issues covered are relevant to clinical trial software and software for design and manufacture of therapeutic goods.

Over the past decade, software has become increasingly important in medical devices and digital adoption more broadly, with rapid innovation in technology driving significant changes. Advances in computing technology and software production have led to a large increase in the number of software-based medical devices available on the market, requiring ongoing review and implementation of reforms to ensure patient safety. We continue to closely monitor and respond to evolution within the sector to ensure that Australia's regulatory framework effectively identifies, mitigates and addresses risks posed by the increasing use of AI.

Established structures and processes for both regulating medical devices incorporating software, and conducting continuous assessment of our regulatory framework to ensure regulation remains appropriate, include:

- refinements and amendments to the regulation of medical device software introduced in 2021
- active membership of both the International Medical Device Regulators Forum (IMDRF) Software as a Medical Device Working Group and the IMDRF Artificial Intelligence/Machine Learning Working Group
- establishment of a Technical Reference Group for software and AI-enabled medical devices to provide expert knowledge on complex issues relating to software and AI technologies
- a dedicated software as a medical device (SaMD) technical team for software pre-market and compliance activities
- a team dedicated to researching and keeping abreast of emerging technology who undertake legislative review and refinements where appropriate or necessary, and
- active participation in review of the *PIC/S Guidelines to Good Manufacturing Practice for Medicinal Products,* Annex 11 Computerised Systems, addressing requirements for international harmonisation of the Pharmaceutical Inspection Convention with the EU AI Act, and subordinate legislation.

Outcomes from our review include findings across the following areas:

- Legislation
- Regulations
- Legislative instruments
- Guidance
- International harmonisation

An additional background section is provided with more information about:

- Our approach to the review
- The consultation process
- Our current framework for regulation

[1] Section 41BD of the *Therapeutic Goods Act 1989*

1.1 Legislation

The *Therapeutic Goods Act 1989* (the Act) is the primary legislation governing the regulation of therapeutic goods in Australia. The Act has measures to ensure:

- appropriate pre-market assessment of therapeutic goods to establish quality, safety, efficacy (for medicines) and performance (for medical devices)
- ongoing review of the safety, quality and efficacy/performance of therapeutic goods, and
- corrective measures can be taken when an issue is identified with a therapeutic good.

During our review, a primary issue identified with the Act relates to the use of language including the scope of the current definitions and their implications for specific activities regulated under the Act.

1.1.1 Definitions

As the use of software develops, terminology and definitions have emerged to describe entities with regulatory obligations across the lifecycle of software products, models and systems. In some jurisdictions, including in Europe, new terms for entities in the AI lifecycle such as “developer”, “deployer” and “distributor” have been included in legislation. Similar terminology has been proposed by DISR in their public consultation where both developer and deployer were proposed, along with “end user”.

These definitions are not currently used in the Act, although the definition of a manufacturer[2] and sponsor[3] align to some degree with the described functions of some of these alternative terms. We asked stakeholders whether the existing definitions within the Act were sufficient and, if not, whether explaining how they apply in guidance would be sufficient or whether we should amend them within the legislation itself.

Stakeholders indicated:

- The definition of a “manufacturer” is not one recognised by stakeholders in the software sector or clinical practitioners who may be involved in a manufacturing activity as a part of clinical practice.
- Clarity is required to determine who is a “sponsor” for the purposes of Australian regulation specifically where a software product that meets the definition of a medical device is made available by a provider located overseas, through an online platform hosted by an Australian-based legal entity.
- Further review, and either refinement of existing definitions or clarification through guidance, is needed to ensure clarity between definitions in the Act and terminology used elsewhere.

Stakeholders also asked for further consultation to be conducted and consideration of:

- the addition of other terms relating to software to therapeutic goods legislation, and
- additional clarification for existing definitions and terms when specifically applied to software (what represents a “substantial change”, for example).

Finding 1

A further review of legislative definitions is required to determine whether:

- refinements to the definitions in the Act are needed; or
- guidance explaining how the current definitions align with emerging definitions like “developer” and “deployer” is sufficient.

[2] Section 41BG *Therapeutic Goods Act 1989*

[3] Section 3 *Therapeutic Goods Act 1989*

Further consultation should be conducted to determine whether other terms relating to software should be included in therapeutic goods legislation or additional clarification to existing definition provided in guidance.

1.1.2 Supply

AI as a medical device presents unique challenges to the existing regulatory framework, as it is frequently accessed and used within virtual and online environments where traditional supply controls are not effective. The ease with which information can be exchanged and propagated is challenging regulators to consider whether current frameworks can be applied to emerging technologies, particularly where:

- a product can be quickly and easily adapted by a user or applied to a purpose not intended by the original developer
- products are hosted on overseas servers where the regulator may not have jurisdiction
- the development and deployment of software products takes place between entities who have not considered the existing framework and how it may apply to the product they jointly develop and deploy, and
- software or AI is developed within a facility or institution for in-house use only.

We asked whether the existing definition of supply and measures for the regulation of supply activities are sufficient, given the platforms and emerging practices associated with the use of software based medical devices. Throughout the consultation processes undertaken during this review, stakeholders indicated there is general confusion about how new methods of supply through online platforms are regulated.

Currently, the definition of "supply" is linked to the primary role of a sponsor, which has regulatory responsibility and obligations under the Act. In addition to clarification or amendment of the definitions of manufacturer and sponsor, stakeholders indicated consideration should be given to amending the definition of "supply[4]" to include that the responsibilities of "access" to a medical device through online, virtual or digital means is captured appropriately.

Finding 2

A review of the definition of "supply" in the Act is needed to ensure access to software-based devices through online, digital or virtual means is appropriately reflected in the Act.

1.1.3 Responsibility

AI models and systems have changed the way therapeutic goods are deployed and used. Use cases are emerging where AI models and systems are replacing some services and activities traditionally performed by human beings. The Act regulates manufacturers and sponsors of medical devices, assigning penalties for offences where a "person" undertakes certain activities. We asked whether the current penalties and offences are sufficient to identify the appropriate person or entity who is responsible for deploying an AI model or system that undertakes a prohibited activity.

Stakeholders expressed concern that the responsibility for the outcomes of deployed AI cannot be appropriately placed using the existing legislation where an output from a deployed system represents an offence under the Act. Given the inclusion of strict liability offences, where responsibility for an offence is not dependent on the ability to show fault or intent, further review of the existing language

[4] Section 3 *Therapeutic Goods Act 1989*

in the Act is needed to ensure responsibility can be appropriately assigned for the outputs of a deployed AI, particularly where:

- AI replaces services traditionally provided by a human, and
- the person who deployed the AI was not aware of the outputs that constituted an offence under the Act.

Finding 3

Further review and consultation should be conducted to determine whether the language used in the Act for offences continues to assign responsibility to the appropriate entity across the AI lifecycle.

Continued collaboration should occur with both the Australian Health Practitioner Registration Agency (Ahpra) and the Australian Commission of Safety and Quality in Health Care to ensure appropriate governance of clinical practice of AI use aligns with the TGA's regulation of therapeutic goods.

1.1.4 Compliance

Stakeholder feedback during the review confirmed the use of AI products is already prevalent within the healthcare sector, driven by benefits including increased efficiency, improved patient health outcomes, cost reduction, improved accessibility and capability. There are, however, a number of issues associated with the use of these products, both observed and reported, including:

- lack of understanding about what products meet the definition of a medical device and are therefore regulated by TGA. For example:
    - Not all AI products used in the healthcare sector meet the definition of a medical device and many, including digital scribes used in clinical practice, have therefore not been assessed for quality, safety or performance before deployment and use.
    - There are instances where software products do meet the definition of a medical device, but the deployer may not realise they are regulated by the TGA. This results in medical devices that have been made available without an appropriate pre-market assessment to ensure the quality, safety and performance of the device.
- inappropriate use of AI-enabled products due to a lack of understanding or misinformation about their intended purpose. For example:
    - In many cases, users are either not aware of the limitations of the AI products they're using or have become complacent over time- one example is not continuing to check outputs as rigorously following a brief "trial" period.
    - AI products are frequently used for functions beyond their original intended scope by users, resulting in applications to circumstances where the performance of the AI has not been validated or verified.
    - Developers of digital scribes claim they are not a medical device as their intended purpose is to summarise clinical practice notes. Users report digital scribes frequently propose diagnosis or treatment options for patients beyond the stated diagnosis or treatment a clinician has identified during consultations. This functionality indicates digital scribes meet the definition of a medical device and require pre-market approval and inclusion in the Australian Register of Therapeutic Goods (ARTG) and are potentially being supplied in breach of the Act.

Beyond healthcare settings, the increasing ease of access to technology including complex open-source software and open datasets for free, or relatively low cost, is encouraging exponential growth in the design and development of innovative software products. The use of online platforms and app stores also allows rapid deployment with minimal opportunities for regulatory oversight.

The TGA has observed, and stakeholders report, an unwillingness from some developers to provide the accountability, transparency and responsibility necessary for engagement with existing regulation.

Developers have expressed views that healthcare providers should take responsibility for validating and verifying the outputs of the deployed systems they choose to use, while simultaneously limiting access to information about the datasets used to train their product or to test the model used to operate it.

It is likely that the time and costs associated with regulatory requirements appear to developers to be disproportionate when compared to the time and costs associated with the development of a software product. A further cultural issue is the pervading belief among some developers that software products don't present a meaningful risk to consumers and users, particularly when they are integrated with the provision of healthcare, where a human is in the loop, or where outputs are information only.

Stakeholders, including clinicians and consumers who use these kinds of products, have identified that the absence of humans, lack of transparency and failure to engage with existing regulatory requirements represent a combination of circumstances that may lead to patient harm. In many instances, users are not aware that AI or machine learning has been used in the development of software, or is used operationally within the clinical workflow.

Finding 4

Targeted action is needed to improve compliance including:

- ongoing direct and improved engagement with the software sector for educative purposes
- development of additional guidance and information resources to support the software sector with understanding their regulatory obligations, and
- compliance action to remove unapproved medical devices from the Australian market.

A review of digital scribes is needed to determine whether they are medical devices and, if so, whether they comply with existing regulatory requirements.

Continued collaboration should occur with both Ahpra and the Australian Commission on Safety and Quality in Health Care to support strengthening of informed consent practices.

1.2 Regulations

Where a software product meets the definition of a medical device, it will be subject to both the Act and specific requirements in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations). Requirements for medical devices in the Regulations include:

- safety and performance requirements for medical devices, known as the "essential principles"
- conformity assessment procedures- processes for the systematic and ongoing examination of evidence and procedures to ensure that medical devices, including IVD medical devices, comply with the essential principles, and
- risk-based classification rules to determine which conformity assessment procedures must be undertaken.

1.2.1 Classification rules

The TGA, like many other regulators around the world, uses a risk-based approach to the regulation of medical devices. What the device is intended for, who it is intended for and how it operates contribute to the overall risk profile of a device. The classification rules are the legislative basis for determining the level of pre-market scrutiny applied to a medical device based on these risk-based factors.

We asked stakeholders whether the current framework for classification is appropriate for the increasing use of AI models and systems, particularly whether the current classification rules for AI

models and systems that make a prediction or prognosis remain appropriate. Currently these kinds of devices are classified as low risk, and do not require a pre-market assessment by an independent third party.

Stakeholder feedback indicated that the current classification rules are largely appropriate for use in devices that are, or include, an AI model or system. However, the increasing complexity of devices used to provide a prognosis or prediction was raised, as these kinds of devices are increasingly used to determine whether a patient will receive a treatment or an intervention. Currently these kinds of devices are classified as low risk, and do not require a third-party assessment before they are deployed. Some stakeholders indicated that this may no longer be appropriate as reliance on their outputs for determining patient care is likely to increase in the future.

While consideration may be needed for the reclassification of these devices, stakeholders recommended a future review take place:

- when more information about these kinds of devices and their use is available, and
- at a time when other jurisdictions are considering a similar classification rule change.

Should specific rules be introduced for prediction and prognosis, changes should align with the approach taken with the current classification rules where classification depends on the seriousness of the condition and whether the device is intended for use by a clinician or consumer.

Finding 5

A future review of the existing classification rules is needed for predictive or prognostic functionality.

No changes should be made to the existing classification rules at this time.

1.2.2 Essential principles

All manufacturers of medical devices must hold evidence demonstrating compliance with legislative requirements for safety and performance, known as essential principles (EPs). The principles are technology-agnostic and non-prescriptive, and relate to aspects of a device where risks may arise. Appropriate mitigation of those risks must be achieved by the manufacturer of the device, who must be able to provide evidence that all relevant EPs have been addressed.

We asked stakeholders whether all of the EPs remain appropriate in the context of AI technology, including EP12.1 which sets out the specific requirements for programmed or programmable medical devices or software that is a medical device.

While the current EPs remain appropriate for use in devices that are, or include, an AI model or system, stakeholders indicated there are specific issues that need to be addressed or clarified within the existing principles and the conformity assessment procedures.

These issues include:

- validation of adaptive and generative AI
- use of open datasets and open-source software
- performance reporting in clinical settings
- labelling, and
- instructions for use.

Consideration of the amendment of the essential principles, and potentially the conformity assessment procedures, may be required in the future as regulation of these technical aspects develops. Further detail on these issues can be found in the section on guidance.

Finding 6

No changes should be made to the existing essential principles at this time.

More extensive guidance, with examples demonstrating how the existing Regulations would apply to specific use cases, is needed.

1.2.3 Regulation for specific AI types and subtypes

AI is a collective term representing a number of subtypes, including:

- **General-purpose AI (GPAI)**: a type of AI system or model used in a broad range of tasks and applications, both intended and unintended by developers
- **Generative AI model***:* an AI model capable of generating content such as images, text, and other media with similar properties to its training data
- **Large language models (LLMs)**: a type of AI model trained on language datasets so they can recognise and generate text emulating human language
- **Machine learning**: a set of techniques that can be used to train AI models to improve performance at a task based on data
- **Deep learning models**: trained using methods of learning that teach a machine how to process data in a similar fashion to a human brain, deep learning models can be used to recognise complex patterns and produce accurate insights and predictions.
- **Neural networks**: comprising layers of artificial neurons, neural networks are a subset of machine learning capable of classifying and clustering data at high velocity to provide incredibly fast real time processing.
- **Narrow AI system**: a type of AI system or model that is focused on defined tasks typically used to address a specific problem. Unlike GPAI models, these types of AI systems cannot be used for a broader range of problems without being re-designed.

During the consultation period, stakeholders sought clarification on what definition of AI was being used in the review. They expressed concern that regulating AI as a whole or as individual subsets will be challenging because of the variety and complexity associated with these technologies.

The capabilities and applications of the different subtypes of AI are virtually limitless, and it is therefore not appropriate to regulate based on the “kind” (subtype) of AI. Where definitions and clarity about AI types and subtypes are sought, stakeholders felt this would be better achieved through guidance rather than specific regulations.

Finding 7

Specific definitions and legislative requirements should not be introduced for specific subtypes of AI.

Regulatory requirements for devices that are, or incorporate, an AI model or system should remain technology-agnostic and continue to be regulated under the existing framework.

1.3 Legislative instruments

A number of legislative instruments are used in the regulation of therapeutic goods. The two most relevant to the legislative review are:

- Therapeutic Goods (Excluded Goods) Determination 2018
- Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

1.3.1 Excluded software

In 2021 reforms were made to the regulation of software products, including introducing an exclusion of 15 subtypes of software for clarity, where they did not meet the definition of a medical device or because an alternative mechanism for oversight existed that was considered appropriate for managing risks associated with the products. Excluded goods are not regulated by the TGA as therapeutic goods, and therefore are not required to meet TGA's regulatory requirements.

The TGA has been monitoring these exclusions, and has identified that the emerging complexity of some excluded software products coupled with the increasing use of AI means some exclusions may no longer be appropriate. We asked stakeholders whether the current 15 exclusions remain appropriate, and to identify the most likely to require further review and refinement such as:

- consumer health products
- digital mental health tools
- software that is a calculator, and
- laboratory information management systems.

The TGA is also aware of work by the Department and the Digital Health Agency to develop a mobile health apps framework, for non-TGA regulated applications, to guide developers and users.

Finding 8

While the majority of the software exclusions remain appropriate, guidance is needed to better support stakeholders with understanding the conditions of exclusion.

The digital mental health tools exclusion is no longer appropriate and urgent review is needed, in collaboration with the Australian Commission on Safety and Quality in Health Care.

Ongoing monitoring and review are needed for health and wellness applications with claims or functionality that may meet the definition of a medical device.

1.3.2 Advertising and transparency

A consistent theme from stakeholders across all cohorts throughout the review was for more information about therapeutic goods, including:

- ability to identify when a good has been assessed or approved by the TGA, and
- access to information about what assessment or approval involves, such as what information has been assessed, what requirements have been met etc.

Stakeholders acknowledged the utility offered by a future Unique Device Identification (UDI) system to assist with transparency. While the TGA has made changes to the ARTG to improve access to information about goods approved for supply in Australia, these do not meet the needs of stakeholders, who want more information about all therapeutic goods, including software based medical devices. This includes access to information such as:

- the model and/or trade name(s) for ARTG included goods
- what inclusion in the ARTG means- what has been assessed, what does "approval" mean- and
- specific intended purpose or indications of the good.

For software-based medical devices, stakeholders are seeking more information, including:

- whether the device is, or operates using, an AI model or system, and information about the datasets that have been used to train and test the AI
- greater transparency regarding updates and new versions to help assess whether the outputs of a product are likely to change as a result, and

- in-app or in-product notifications tied to risks the user should be aware of when using it.

While many of these concerns can be addressed with guidance about how to apply existing regulations, changes may also be needed to advertising provisions within the Therapeutic Goods Regulations 1990 and the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Code). The Code sets out minimum requirements for advertising therapeutic goods to the public. There is also a provision to require specific information be included in advertising, and to allow the use of certain representations for categories of goods. The Act contains criminal offences and civil penalties for advertising to the public in a manner that does not comply with the Code.

Finding 9

A review of the advertising provisions in the Therapeutic Goods Regulations and the Code is needed to identify changes that could be made to improve transparency and access to information about therapeutic goods and how they are assessed and approved by the TGA, including when accessing digital therapeutic goods through virtual and online environments.

Targeted review and consultation with stakeholders are needed to further enhance measures like UDI to include software and AI-related details for both standalone software and software incorporated in a medical device.

1.4 Guidance

AI models and systems are used in a myriad of ways, including (but not limited to):

- in the design and manufacturing process
- in clinical trials for therapeutic goods, and
- where it is, or is incorporated within, a therapeutic good.

A key finding of the review is that while the existing framework's legislation and regulations are largely fit-for-purpose, there is a lack of information available about how the existing framework should be applied to emerging use cases of AI.

Guidance is an important tool published by the TGA to support both regulatory and compliance activities. It helps sponsors to understand the regulatory requirements and offers flexibility in how regulations are implemented.

Stakeholders noted that while many guidelines and standards relating to the regulation of therapeutic goods and provision of healthcare services exist, there are few resources explaining how they should be applied to emerging technologies, including AI. Feedback during the review identified specific areas where more information is needed and the barriers to the development of these resources, particularly regarding technical aspects of medical device regulation, including:

- Continuous change control for adaptive AI
- Use of datasets and software of unknown provenance
- Performance reporting

1.4.1 TGA website

Stakeholders from different cohorts provided feedback on information available through the TGA website and other resources. In relation to the TGA website.

- There is an overall lack of resources and information available for members of the public who use therapeutic goods, including both consumers and clinicians.
- Information on the TGA website, particularly for medical devices, is not well organised and finding it is difficult without the use of Google or similar search engines.

- There is a lot of information and guidance about the regulation of software available on the website, but it is poorly organised, difficult to find, lacking in key areas and not well updated as developments in the field occur.
- Many of the compliance matters identified in the review relate to a lack of available information accessible in places where stakeholders would look for it.
- Consideration should be given to the development of resources beyond guidance documents on the website including videos, fact sheets, etc available through social media platforms and linked to places where people might look for them including the Department website.

Finding 10

A general review of the TGA's website, including layout and content, is needed.

- Specific content and landing pages for consumers and health professionals should be reinstated.

A review, consolidation and update of guidance and information available on the TGA's website for software based medical devices, including AI, is required.

Guidance should:

- be easy to locate on the TGA's website
- use example use cases to show how the existing regulatory framework is applied
- explain how the existing legislation and regulations apply to the various AI subtypes, and
- incorporate links to guidance from other regulators for matters like privacy.

1.4.2 Continuous change control for adaptive AI

Current regulatory approaches are based on assessment of static or "locked" models and systems, where:

- the safety, performance and effectiveness of medical devices are assessed before deployment, and
- the ongoing performance of the device once deployed is monitored through post-market monitoring systems and reporting of adverse events and maintained through recalls.

Device manufacturers are currently required to notify the TGA or certifying body of significant changes to their medical device, including if these changes alter the intended purpose. Sponsors must ensure the currency of information in the ARTG is maintained.

Medical devices that are, or incorporate, adaptive or generative AI have the capacity to alter functionality over time with or without direct manufacturer oversight. The current regulatory framework has not yet been tested against devices that are constantly evolving, and it may be difficult to identify when a significant change has occurred. Using the existing processes for reassessment is likely to become both costly and time consuming for sponsors and manufacturers/developers.

Regulators around the world are currently considering the most appropriate methods for change control, including validation and ongoing monitoring of performance. The lack of agreed guidelines and standards determining acceptable parameters for validation and verification of adaptive models and systems was raised by a number of stakeholders. While currently there are few examples of generative or adaptive AI as medical devices, the TGA has noted that these resources are in development. Currently, in most instances, change control is determined by developers and assessors of AI on a case-by-case basis driven by the specific purpose of the model or system.

Some stakeholders noted continuously adapting AI likely warrants constant monitoring and real time continual review or evaluation of performance to ensure the quality of outputs doesn't degrade over time. It is noted that these approaches are likely to be impractical without involving further AI models

and systems tasked with conducting rolling review, although some international jurisdictions have mandated human oversight measures be present before putting AI models and systems into service. This includes Europe, where the AI Act mandates human oversight measures for high-risk AI systems.

Stakeholders voiced a desire for clear guidance regarding what constitutes a 'significant change' in the context of software as a medical device, and more information about the regulatory processes associated with assessing and approving changes in adaptive models and systems.

While explicit standards relating to AI used in, or as, a medical device are still in development, there are a number of applicable standards for AI[5], and work to ensure they remain current is ongoing. Compliance with standards is a critical way a sponsor can meet the TGA's regulatory requirements. Work is ongoing with international regulators to ensure a consistent approach, including the use of pre-approved change control plans (PCCPs) and what types of changes can be included in a PCCPs. PCCPs would describe planned changes to be made to a device post-approval, and how these changes will be developed, validated and implemented. These are discussed further in section 2.3.4-International harmonisation.

Finding 11

Guidance for technical requirements for adaptive and generative AI should be developed as expeditiously as possible.

1.4.3 Use of datasets and software of unknown provenance

Beyond adaptive AI models and systems, the use of datasets or software of unknown provenance within medical devices or as training datasets for medical devices poses a further challenge to regulators seeking to establish appropriate pathways to validation of devices prior to market entry. Currently the use of datasets or software is a matter for developers, who must decide on a case-by-case basis the most appropriate datasets or software within their device design process. Justification for the use of these resources and demonstration of their validity is also a matter for the developer since, as with adaptive AI, there are currently no explicit guidelines or standards available for those who choose to utilise options of unknown provenance[6].

Use of software and datasets of unknown provenance is addressed in several standards[7] where the associated risks can be managed. The increasing development and deployment for use of resources of unknown provenance that have not been validated by reputable software vendors is compounding the issue, placing pressure on developers to independently validate datasets without access to information about their origin or the accuracy of their reference standards. The development of innovative devices trained on unvalidated open datasets is an emerging issue for regulators, as

[5] ISO/IEC 22989:2022 Information technology — Artificial intelligence — Artificial intelligence concepts and terminology
ISO/IEC 5338:2023 Information technology — Artificial intelligence — AI system life cycle processes
ISO/IEC 8183:2023 Information technology — Artificial intelligence — Data life cycle framework
ISO/IEC 42001:2023 Information technology — Artificial intelligence — Management system
ISO/IEC 42005 Information technology — Artificial intelligence — AI system impact assessment (under development)
DIN/TS 92004 - Artificial intelligence – Quality requirements and processes – Risk identification and analysis for AI systems along the entire life cycle

[6] Noting the IMDRF published "Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity" in 2023. Software Bill of Materials can improve transparency and used to identify compliance issues and operational challenges as well as and mitigate security risks throughout the software supply chain.

[7] Use of software of unknown provenance is covered in IEC 62304: Medical Device Software – Software Life Cycle Processes
Use of datasets of unknown provenance is covered in:

- ISO/IEC 5338:2023 Information technology — Artificial intelligence — AI system life cycle processes
- ISO/IEC 8183:2023 Information technology — Artificial intelligence — Data life cycle framework
- ISO/IEC 42001:2023 Information technology — Artificial intelligence — Management system

developers seek more information about acceptable validation for medical devices that incorporate software of unknown provenance or are trained on open datasets.

Finding 12

Guidance for the use of open datasets and software of unknown provenance should be developed as expeditiously as possible, with reference to applicable available standards.

1.4.4 Performance monitoring

The performance of AI depends on the robustness of the datasets used to train the model or system. As the use of AI becomes more prevalent within healthcare settings, ongoing monitoring will become critical to ensuring ongoing accuracy and improvement of performance. This would include within the institution of deployment, including health providers who are using AI in practice settings.

While mandatory adverse event reporting for healthcare facilities is currently being addressed by the TGA through regulatory reform, stakeholders from the software sector and clinical practice have indicated data from in-clinic performance of deployed AI models and systems will not only be a critical component of monitoring and evaluation, but will likely be central to the ongoing accuracy and improvement of these kinds of models and systems.

The TGA notes the Office of the Australian Information Commissioner's 21 October 2024 publication *New AI guidance makes privacy compliance easier for business*, which includes:

- a guide to aid businesses with complying with privacy obligations when using commercially available AI products, and
- privacy guidance for developers using personal information to train generative AI models.

The TGA will provide feedback for consideration to the Office of the Australian Information Commissioner from stakeholders relating to privacy matters.

1.4.5 AI use in the healthcare sectors

As the use of medical devices becomes more closely entwined with service delivery and integrated with the provision of healthcare, stakeholders beyond manufacturers and sponsors are seeking access to more information about the therapeutic goods they use. Stakeholders, including consumers and clinicians, sought more guidance and information to explain how to safely develop, deploy and use products that are, or incorporate, AI models and systems. This included:

- how to determine the limitations and applications of products that are, or contain, an AI model or system
- access to information about the specific datasets used to train and test AI models and systems
- the ability to determine how products are regulated and what information has been assessed as a part of the approval process, and
- how to identify when they are undertaking activities that will meet the TGA's definition of a manufacturer or sponsor, and therefore incurring regulatory obligations.

The TGA notes the publication of resources from other regulators and peak industry groups and bodies about the safe use of AI, including:

- Ahpra: *Meeting your professional obligations when using Artificial Intelligence in healthcare*[8]

[8] https://www.ahpra.gov.au/Resources/Artificial-Intelligence-in-healthcare.aspx

- The Royal Australian College of General Practitioners (RACGP): *Artificial intelligence (AI) scribes*[9]
- Australian Commission on Safety and Quality in Health Care: *AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, and Evidence about Quality and Safety*[10]

Finding 13

More information and resources should be developed for stakeholders beyond members of the medical device industry, including:

- consumers and healthcare practitioners, to promote an understanding of the limitations of AI-enabled products and evaluate the appropriateness of a product for use, and
- developers and deployers, to aid them with developing appropriate labels, warnings and instructions for use to help users of their models and systems mitigate known and residual risks when using the product.

Guidance and information needs to be accessible through a range of portals including social media platforms.

1.5 International harmonisation

The TGA is active in a number of international activities and, where possible, seeks to align with approaches taken in other jurisdictions. As a relatively small jurisdiction in the global therapeutic goods market, Australia strives for international harmonisation in our regulatory framework wherever appropriate. Over 85% of devices supplied in Australia - excluding self-certified devices such as Class I non-sterile, non-measuring- are imported using overseas certification. Mutual recognition and the ability to use evidence and certification from comparable overseas regulators streamlines the Australian process for sponsors who are supplying their therapeutic goods to our market. This alignment reduces costs and lead times for Australian consumers seeking access to therapeutic goods.

Stakeholders noted the need to preserve international harmonisation of Australia's regulatory approach, to ensure innovative devices can be safely and deployed as early as possible, while limiting the regulatory burden for sponsors of these devices. Further comments were received on the changes occurring in other jurisdictions where different approaches have been taken with respect to meeting the challenges associated with regulating AI.

1.5.1 International approaches to AI

AI is a broad term encompassing several different technologies and applications. There are examples of AI models and systems already regulated using existing legislative frameworks. For more recent and emerging examples of AI, regulatory approaches continue to develop as these products enter the market. The largest therapeutic goods regulator in the world, the US FDA, maintains a list of Artificial Intelligence and Machine Learning-Enabled Medical Devices on their website and, as at 7 August 2024, had approved 950 devices.

Regulatory approaches to the regulation of AI are still developing, with new legislation, policies and guidelines appearing in the last twelve months. While relevant international standards and guidelines

[9] https://www.racgp.org.au/running-a-practice/technology/business-technology/artificial-intelligence-ai-scribes

[10] https://www.safetyandquality.gov.au/publications-and-resources/resource-library/ai-implementation-hospitals-legislation-policy-guidelines-and-principles-and-evidence-about-quality-and-safety

do exist[11], there is a continuing struggle to ensure these documents keep pace with rapid changes in the regulated environment. The International Medical Device Regulators Forum (IMDRF) is actively working on Guiding Principles for Good machine learning practice for medical device development, and a technical framework for AI lifecycle management for medical devices. In the meantime, pre-market conformity assessment must be conducted on a case-by-case basis using the existing regulatory framework, which stakeholders have indicated appears to be both robust and flexible enough for the task provided guidance is developed to explain its application.

Finding 14

Strong engagement with therapeutic goods regulators in other jurisdictions must be maintained to share information about the developing regulatory approaches to AI and leverage learnings from other jurisdictions.

International harmonisation with comparable jurisdictions should be maintained as far as possible, in order to minimise regulatory burden and the disruption to supply of innovative devices.

The Australian framework for regulating medical devices should be responsive and reactive to developments in other comparable jurisdictions and the identification of specific risks with respect to AI, rather than proactive.

[11] AI-specific:

- ISO/IEC 22989:2022 Information technology — Artificial intelligence — Artificial intelligence concepts and terminology
- ISO/IEC 5338:2023 Information technology — Artificial intelligence — AI system life cycle processes
- ISO/IEC 8183:2023 Information technology — Artificial intelligence — Data life cycle framework
- ISO/IEC 42001:2023 Information technology — Artificial intelligence — Management system
- ISO/IEC 42005 Information technology — Artificial intelligence — AI system impact assessment (under development)
- DIN/TS 92004 - Artificial intelligence – Quality requirements and processes – Risk identification and analysis for AI systems along the entire life cycle
- AAMI CR34971:2022: Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning

General medical device software:

- IEC 62304: Medical Device Software – Software Life Cycle Processes
- IEC 62366: Medical Devices - Application of Usability Engineering to Medical Devices
- ISO 13485: Medical devices -- Quality management systems -- Requirements for regulatory purposes is a voluntary standard
- ISO 14971: Medical devices — Application of risk management to medical devices

2. Background

2.1 Approach to the review

The TGA is Australia's government authority responsible for regulating products that meet the legislative definition of a therapeutic good under the *Therapeutic Goods Act 1989* (the Act). These products include medicines, medical devices and biologicals to help Australians stay healthy and safe. Regulation includes evaluating, assessing and monitoring products that generally require pre-market approval and inclusion on the Australian Register of Therapeutic Goods (ARTG) before they can be imported, exported or supplied in Australia.

2.1.1 Scope

The scope of our review incorporated the Act and all subordinate legislation, including:

- Therapeutic Goods Advertising Code
- Therapeutic Goods Regulations 1990
- Therapeutic Goods (Medical Devices) Regulations 2002
- Therapeutic Goods (Excluded Goods) Determination 2018

The review considered use cases and applications of AI models and systems, including:

- within therapeutic goods, where an AI model or system is, or is incorporated within, a therapeutic good
- where AI is used within the design, development or manufacturing process of a therapeutic good, and
- AI models and systems used within the healthcare sector more generally (i.e. where the model or systems is not a therapeutic good) when intersecting with therapeutic goods or the Therapeutic Goods Administration.

2.1.2 Out of scope

While we recognise the importance of the following areas of regulation, they are not within the TGA's legislative remit and were therefore not included as a focus in the TGA's review:

- **Privacy:** In Australia the *Privacy Act 1988* promotes and protects the privacy of individuals through 13 Australian Privacy Principles that apply to Australian Government agencies and organisations, including the TGA. The Office of the Australian Information Commissioner (OAIC) is the independent regulator for privacy and freedom of information. More information about the Privacy Act 1988 can be found on the OAIC website. The way the TGA manages personal information is explained in our privacy policy. The Department's privacy policy webpage also contains information about how the Department manages personal information with links to further relevant information about privacy.
- **Cyber security:** In Australia the government's approach to cyber security is outlined in the 2023-2030 Australian Cyber Security Strategy (the Strategy), and implementation of the Strategy is supported by the Australian Signals Directorate's Australian Cyber Security Centre (the Centre). While the TGA continues to engage with the Centre to ensure threats to cyber security are addressed, the Strategy and associated laws enforcing cyber security more generally were not a part of the TGA's legislative review.
- **Clinical practice:** Clinical and healthcare practice are not regulated by the TGA, including where health professionals and practitioners are using AI capability that does not meet the legislative definition of a medical device, such as virtual assistants used to summarise

practice notes or manage patient records. Clinical practice and healthcare facilities are regulated through:

- The Australian Health Practitioner Regulation Agency (Ahpra) working in partnership with the National Professional Boards to ensure that Australia's registered health practitioners are suitably trained, qualified and safe to practise.
- The Australian Commission on Safety and Quality in Health Care, who lead and coordinate national improvements in the safety and quality of health care. Their work includes developing and administering standards aimed at better informing, supporting and organising Australia's health system. The standards help to ensure the health system can deliver safe and high-quality care, can keep people safe when they receive health care and to ensure they receive the health care they should.

2.2 Consultation

Consultation with a wide range of stakeholders has been a key feature of the TGA's legislative review, and included three key processes:

1. Targeted stakeholder consultation sessions
2. Joint webinars with the Department of Industry, Science and Resources (DISR)
3. Public consultation

2.2.1 Targeted stakeholder consultation sessions

A series of targeted stakeholder consultations was conducted to identify areas of strength and where improvements could be made, including any areas of concern across the therapeutic goods and healthcare sectors. Fourteen sessions were conducted with 305 stakeholders participating. Stakeholders included:

- clinicians and health professionals from within the Department
- members of the Technical Reference Group for Software as a Medical Device (SaMD) and Artificial Intelligence (AI)
- regulatory experts from the TGA's Regulatory and Technical Consultative Forum for Medical Devices (RegTech)
- software developers and technical experts, including the Medical Software Industry of Australia and ANDHealth clients
- health care providers, including representatives from professional associations and primary care physicians
- consumer representatives from the TGA's Medical Devices Consumer Working Group (MDCWG), and
- representatives from the TGA's Point-of-care Manufacturing of Medical Devices Steering Committee and Working Groups

The format of these sessions included:

- an information guide to inform participants about the topics and questions to be discussed
- a PowerPoint presentation with information about the review, relevant case studies, and examples from other jurisdictions, and
- use of Miro, an online virtual whiteboard platform for capturing thoughts and comments from participants both during the session and in the week following.

During the sessions stakeholders identified:

- where AI systems and models are currently used
- emerging uses of AI systems and models
- issues and concerns both observed and likely to emerge, and
- key areas of legislation, regulation and guidance requiring review.

2.2.2 Joint webinars with DISR

Two sessions were conducted jointly with DISR to support their public consultation process- *Introducing mandatory guardrails for AI in high-risk settings: proposals paper*. 148 people attended these webinars.

The format of these sessions included:

- a PowerPoint presentation from DISR outlining the topics from the DISR consultation document
- a PowerPoint presentation from the TGA explaining how the current framework for the regulation of therapeutic goods is mapped to the proposed guardrails, and
- use of Miro, an online virtual whiteboard platform for capturing thoughts and comments from participants both during the session itself and in the week following.

2.2.3 Public consultation

On 12 September 2024 the TGA published a public consultation paper. Two webinars were held in support of the paper, and 217 people attended. The public consultation closed on Sunday 20 October. 53 responses were received.

The key themes we sought feedback on, outlined in the Consultation paper, included:

- **Potential changes to language and definitions:** Existing legislation was developed in an environment where therapeutic goods were predominantly physical products and activities related to their supply almost always conducted by human beings. We asked about measures that may be needed to address issues associated with the rising number of software-based medical devices and their availability through virtual platforms, as well as whether the current legislation appropriately provides for the increasing conduct of activities by AI instead of humans.
- **Potential changes to the Medical Devices Regulations:** Where an AI is intended for a purpose that aligns with the legislative definition of a medical device, it will be regulated by the TGA and will need to meet all relevant regulatory requirements. Currently the TGA's framework for regulation is technology-agnostic, with a risk and principles-based approach. We asked whether this approach remains appropriate, and whether refinements are needed to ensure clarity and strength.
- **International harmonisation:** A globally harmonised approach to the regulation of medical devices is key to facilitating appropriate and cost-effective regulation and timely access to products. We asked about the risks and/or advantages of maintaining international harmonisation.
- **Review of currently excluded software:** A number of software products are currently excluded from TGA regulation, as they do not meet the definition of a medical device or do not have a therapeutic purpose. The increasing use of AI impacts how these kinds of products are evolving. We asked about the appropriateness of these exclusions into the future.
- **Transparency:** Stakeholders across all cohorts, particularly consumers and clinicians, have identified transparency as a key issue with the use of AI. Identifying what transparency means in relation to AI, and the expectations of different stakeholders, has been difficult, as:

- AI is a broad term covering multiple capabilities, functionalities and technologies
- the use of AI is already prevalent and integrated within existing systems, to varying degrees, and
- the application of AI within these models and systems is so varied that identifying the use of AI may not always contribute meaningfully to the mitigation of risks. For example, knowing where AI has been used to manage quality control in the manufacture of a medicine is unlikely to provide a real-world benefit or significant risk mitigation to consumers or clinicians.

We asked what transparency means, and what measures could be introduced to address this issue.

- **Guidance, education, information and communication:** During the targeted stakeholder workshops, the majority of participants agreed that the TGA's existing regulatory framework is already robust and provides the flexibility afforded by its technology-agnostic approach. Stakeholders further noted that many of the issues associated with regulation of AI can be attributed to a lack of education, communication, information and guidance about how the existing framework is applied to therapeutic goods that incorporate AI models and systems. We asked respondents to identify where changes or supplementation to the existing material and guidance is needed to provide clarity.

2.3 The current framework

Australia has a well-developed, robust regulatory framework for the regulation of therapeutic goods that includes both pre-market (ex-ante) and post-market (ex-post) measures to ensure the ongoing safety, quality and performance of all therapeutic goods.

Key features of the framework include:

- independent assessment and certification from approved third party regulators and assessment bodies
- use of the ARTG as the basis for maintaining regulatory oversight of most therapeutic goods that are imported into, exported from, or otherwise supplied within Australia
- after a product is approved and included on the ARTG, ongoing reporting and surveillance requirements to ensure products continue to be safe and perform as intended
- a range of criminal and civil penalties that can be applied where there is failure to comply with regulatory requirements, and
- for medical devices, legislative mechanisms ensuring alignment with existing Australian data and privacy laws, as well as capability to require alignment with cybersecurity strategy requirements.

2.4 Medical device regulation

Regulatory requirements for medical devices, including software, are principles-based and apply regardless of whether the product incorporates components like AI, chatbots, cloud, mobile apps or other technologies. As such, software that incorporates generative AI such as large language models (LLMs), text generators, and multimodal generative AI are all regulated as a medical device if they meet the definition under the Act.

As a component of the review, we mapped the existing legislative framework, including regulations and guidance, against the mandatory guardrails proposed for use in high-risk settings under the proposal put forward by DISR in their consultation: Introducing mandatory guardrails for AI in high-risk settings: proposals paper. A summary is at **Attachment A**.

This section documents key features of the existing framework for the regulation of medical devices including:

- Technology agnostic regulation
- Risk based classification
- Principles based regulation
- International harmonisation

2.4.1 Technology-agnostic regulation

Australia's regulatory approach to medical devices is technology-agnostic, with legislative requirements centred on risk and principles rather than linking specific requirements to explicit features or technologies. A technology-agnostic approach requires those responsible for manufacturing a medical device to:

- identify the specific and potential risks associated with the device throughout its lifecycle
- institute measures to mitigate both identified and residual risks
- have measures in place for ongoing review and monitoring of the device's performance after it has been deployed, and
- engage in ongoing review and refinement of the device once deployed.

This approach provides flexibility and responsiveness to emerging technologies, allowing lower risk devices to enter the market expeditiously while subjecting higher risk devices to greater regulatory scrutiny to ensure quality, safety, and performance throughout the device life cycle.

The continuation of a technology-agnostic approach will provide flexibility to ensure appropriate regulation is capable of being applied to emerging technologies without the need for continual review and refinement of legislation. Moving away from a technology-agnostic approach where the onus for demonstrating safety, quality and performance rests with the manufacturer or deployer may lead to the introduction of risks as developers adopt a "tick-box" mentality to regulation rather than a proactive engagement and assessment of the risks posed by their products.

Development of specific regulatory requirements for individual technologies is also likely to become a limiting factor with respect to the development of innovative devices in the long term, as devices that don't easily fit within specified parameters struggle to meet requirements that were never intended for devices of their nature.

2.4.2 Risk based classification

In Australia, devices are classified using classification rules set out in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002.

The classification of a medical device is determined by factors including how long the device will be continuously used for and how invasive the device is. For software-based medical devices, classification may also be impacted by whether the device is intended for use by a clinician or a consumer, and the seriousness of the illness or condition for which it is intended to be used. The classification of a device will determine the level of scrutiny and pre-market assessment applied to the device before it can be deployed/supplied.

2.4.3 Principles based regulation

In Australia, manufacturers are required to demonstrate that medical devices comply with the essential principles. These are legislative requirements that are further set out in Schedule 1 of the

Regulations, and relate to specific characteristics of medical devices including design, construction, evidence supporting the use of the device and information to be provided with the device.

Manufacturers must ensure their devices meet all relevant principles and sponsors must either hold or be able to obtain this evidence from their manufacturer on request. Principles-based regulation, as opposed to prescriptive or rules-based regulation, provides flexibility. This approach accommodates the broad complexity and diversity of medical devices regulated, including as new technologies like AI emerge. A rules-based approach may, for example, require compliance with prescribed requirements including international standards such as ISO or IEC standards.

Demonstrating compliance with the essential principles may include compliance with relevant international standards, but for emerging technologies where an appropriate standard may not yet exist, other approaches may be used. The flexibility to adapt the principles to the unique circumstances of a medical device, particularly those incorporating emerging technologies, allows approaches to evolve over time without continuous review and updating of legislative frameworks.

2.4.4 International harmonisation

Our current approach and commitment to international harmonisation allows sponsors of medicines and medical devices to use international assessment and approvals from comparable overseas regulators to support applications for inclusion of their therapeutic goods on the ARTG.

The TGA is also a member of the IMDRF, which seeks to *"strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges while protecting and maximizing public health and safety."*[12]

The IMDRF has published a significant number of regulatory guidance documents for adoption by jurisdictions globally. Guidance documents are developed through specialised Working Groups and involve global public consultation processes. The TGA is an active member of both the IMDRF Software as a Medical Device (SaMD) Working Group and the IMDRF Artificial Intelligence/Machine Learning Working Group, which have both published a range of guidance documents. The AI Working Group is currently focused on finalising additional guidance on good machine learning practices and new guidance on AI lifecycle management, while the SaMD Working Group is developing an approach to pre-approved change control plans (PCCPs).

2.5 Software regulation and reforms

The TGA regulates AI when it meets the legislative definition of a medical device in Section 41BD of the Act. AI products likely to meet this definition include those intended to be used for the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of a disease, injury or disability.

In recent years, software has become increasingly important in medical devices and digital adoption more broadly. It is also becoming more important as a medical device in its own right. Rapid innovation in technology has driven significant changes to software function and adoption, giving rise to a larger number of devices able to inform, drive or replace clinical decisions, or directly provide therapy to an individual.

Advances in computing technology and software production have led to a large increase in the number of software-based medical devices available on the market, requiring the implementation of reforms to ensure patient safety. Software-based medical devices are medical devices that incorporate software or are software, including software as a medical device, or software that relies on hardware to function as intended, and are regulated in Australia by the TGA.

These kinds of devices may be integrated within electronic health records systems, used by clinicians or health professionals in the provision of care, or used to determine how or when patients will receive

[12] https://w/ww.imdrf.org/

care. Their increasing use, integration in healthcare systems, and complexity have given rise to new regulatory challenges.

In 2021, the TGA introduced a number of regulatory refinements aimed at ensuring the regulation of software-based medical devices, including software that functions as a medical device, remains appropriate and targets the risks associated with these kinds of devices appropriately. Refinements included:

- amendments to the essential principles include the addition of Essential Principle 12.1, which details specific requirements for programmed or programmable medical devices or software that is a medical device
- new classification rules for software based medical devices used for diagnostic or screening purposes to capture their potential to cause harm through the provision of incorrect information
- introduction of an exemption from TGA regulation for certain clinical decision support software, and
- exclusion of certain software products for the sake of clarity, or where existing oversight measures were available through other regulatory frameworks to ensure these products were safe and fit for their intended purpose.

2.5.1 Ongoing reforms

The TGA has well-established structures and processes for ensuring the regulation of emerging technologies, including software based medical devices, remains appropriate. These include:

- strong engagement with other device regulators around the world through direct relationships, IMDRF membership and representation on relevant IMDRF working groups
- representation on key committees and working groups associated with the development of international and Australian standards and guidelines
- well developed relationships with key peak industry, professional and consumer representative group, and
- a number of working groups including, but not limited to:
    - The Medical Devices Consumer Working Group
    - Technical Reference Group for Software as a Medical Device (SaMD) and Artificial Intelligence (AI)
    - Point-of-care Manufacturing of Medical Devices Steering Committee and Working Groups
    - Advisory Committee on Medical Devices

Attachment A – mapping our existing framework to DISR's proposed mandatory guardrails[13]

Proposed DISR guardrail	Current regulatory framework for the regulation of therapeutic goods
Guardrail 1 Establish, implement and publish an accountability process including governance, internal capability and a strategy for regulatory compliance.	The *Therapeutic Goods Act 1989* and associated regulations require the establishment, implementation, and assessment/certification of a quality management system for all manufacturers of medical devices. This system can be assessed and certified either by the TGA or a recognised overseas regulatory body (manufacturer's evidence). There is also provision to recognise another conformity assessment body to perform assessment and certification activities under the TG Act. The TG Act also has criminal and civil penalties for failure to comply with regulatory requirements. An overview of the framework and how it applies can be found on our website here.
Guardrail 2 Establish and implement a risk management process to identify and mitigate risks.	Manufacture of medical devices is subject to assessment and certification, the cornerstone of which is a robust quality management system which includes established processes to identify and mitigate risks associated with the use of the devices. As above, all devices are required to demonstrate they meet the essential principles which includes identification and mitigation of all risks along with a strategy for addressing any residual risks that cannot be directly mitigated through proactive steps (addition of warning labels for circumstances the device may encounter which may inhibit or limit performance on the labelling or in the instructions for use, for example).
Guardrail 3 Protect AI systems and implement data governance measures to manage data quality and provenance.	The medical devices regulatory framework contains general principles and specific principles relating to safety, performance, design, and construction of "programmed or programmable medical device or software that is a medical device", which would generally include medical devices using AI. There are explicit requirements in the Regulations relating to data quality. Data management also falls within the scope of a robust quality management system including but not limited to data collection, annotation, pre-processing, documentation and version control. TGA has published information about our expectations regarding data management and

[13] Many of these guardrails (e.g. 1, 2, 4, 5, 6, 7, 8) relate beyond the AI product lifecycle managed by the manufacturer, to the use of AI in deployment, where TGA's regulatory framework would be supplemented by clinical practice regulation of Ahpra and ACSQHC in close collaboration with the TGA.

	integrity when ensuring compliance with GMP standards for medicines and biologicals.
Guardrail 4 Test AI models and systems to evaluate model performance and monitor the system once deployed.	The manufacturers of all medical devices must have validation and verification test data (evidence) that demonstrates the technical and clinical performance of their device before they can be supplied. When requested, the evidence of validation and verification testing, and other associated documents (including clinical evidence) is required to be submitted for review as part of an application for inclusion in the Australian Register of Therapeutic Goods (ARTG). Once approved, the product can be supplied in Australia Post-market conditions and requirements imposed by our framework require the ongoing monitoring of device performance and corrective action where required.
Guardrail 5 Enable human control or intervention in an AI system to achieve meaningful human oversight.	Manufacture of medical devices is subject to assessment and certification, the cornerstone of which is a robust quality management system which includes established processes to identify and mitigate risks associated with the use of the devices. As per previous responses, all devices are required to demonstrate they meet the essential principles which includes identification and mitigation of all risks along with a strategy for addressing any residual risks that cannot be directly mitigated through proactive steps (addition of warning labels for circumstances the device may encounter which may inhibit or limit performance on the labelling or in the instructions for use, for example). There is also provision to impose conditions of supply on any products that are included in the ARTG
Guardrail 6 Inform end-users regarding AI-enabled decisions, interactions with AI and AI-generated content.	Requirements for labelling and instructions for use require: • Instructions for safe operation • Identification of any risks associated with the device, its use or interactions with external factors which may give rise to risk Measures to ensure that users can identify whether a device is working as intended
Guardrail 7 Establish processes for people impacted by AI systems to challenge use or outcomes.	TGA facilitates reporting of adverse event reports associated with medical devices through our website. This functionality is publicly available. We also make the database for adverse events for both medical devices and medicines publicly

	available. Sponsors (suppliers, importers, etc) are required by legislation to report adverse events. Our medical device Incident Report and Investigation Scheme allows us to detect emerging signals with specific devices that are experiencing adverse events (which includes failure to perform as intended). We have uniform recall procedures to intervene with the supply of a therapeutic good that is not performing as intended, or where there is an emerging issue of concern. Procedures include the power to remove a product from the market, cease supply, recall a product, issue a hazard alert or safety notice, or instruct a sponsor to take a corrective action to address the emerging concern/issue. There are civil and criminal penalties associated with a range of non-compliance with our legislation including supplying goods that are not safe or that do not meet regulatory requirements.
Guardrail 8 Be transparent with other organisations across the supply chain of an AI system or model to help them effectively address risks.	Manufacturers of medical devices are subject to assessment and certification, the cornerstone of which is a robust quality management system which includes established processes to identify and mitigate risks associated with the use of the devices. As above, all devices are required to demonstrate they meet the essential principles which includes identification and mitigation of all risks along with a strategy for addressing any residual risks that cannot be directly mitigated through proactive steps (addition of warning labels for circumstances the device may encounter which may inhibit or limit performance on the labelling or in the instructions for use, for example). This includes transparency with other organisation across the supply chain where risk arises if information is not disclosed. The TGA has legislative power to share information with other governments and international organisations with relevant mutual recognition agreements in place, and to relevant authorities within the Commonwealth, States or Territories, relating to therapeutic goods, health or law enforcement.
Guardrail 9 Keep and maintain records to allow third parties to assess compliance with guardrails.	Monitoring powers are established through our legislation. First, the manufacturers and sponsors have requirements to maintain information about the devices, their safety and performance while the device is being supplied. Second, there are explicit post market requirements including the need to report adverse events and engage with regulatory activities. The final aspect is the powers TGA has to compel sponsors and manufacturers to engage with post-market review, monitoring and recall activities. We

	have mechanisms for taking action against devices that have safety concerns or issues, even when they are emerging and not yet confirmed.
Guardrail 10 Undertake conformity assessments to demonstrate and certify compliance with the guardrails.	The Therapeutic Goods Act and associated regulations require the establishment, implementation and assessment/certification of a quality management system for all manufacturers of medical devices. This system can be assessed and certified either by the TGA or a recognised overseas regulatory body. The TG Act also has criminal and civil penalties for failure to comply with regulatory requirements. Conformity assessment is the process of verifying that the manufacturer of a medical device has demonstrated compliance with all conformity assessment procedures associated with the device. CAPs ensure the device is safe and fit for its intended purposes, and will perform as expected throughout the lifetime of the device.

Therapeutic Goods Administration

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