Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

Review of therapeutic goods legislation

Version 1.0, September 2024

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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Introduction

Artificial Intelligence (AI) has already made a difference to many lives, providing the potential to solve problems faster, and opening up opportunities to get things done in smarter and better ways. If safely deployed, its development and adoption can improve wellbeing, quality of life and economic growth. At the same time, caution is needed as AI presents a potential to create or amplify harms to individuals, organisations, communities and social cohesion through risks associated with its use including inherent bias, accuracy and data quality. These harms may disproportionally affect vulnerable and marginalised groups including people with cognitive disability, displaced workers, older people, culturally and linguistically diverse communities, regional communities, women, girls, gender diverse people and people who are mentally or physically unwell.

Due to the number of unknowns around how AI works in the general public, there is low public trust that AI systems are being designed, developed, deployed and used safely and responsibly, particularly in high-risk settings.[1] People are concerned about personal privacy, the impact of bias and errors, and a near future where people can't tell real from fake.

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 the adoption and use of AI technology in a safe and responsible manner. Through the budget measure for Safe and Responsible AI, the Australian Government is acting to ensure the design, development and deployment of AI systems in Australia in legitimate but high-risk settings, is safe and can be relied upon, while ensuring the use of AI in low-risk settings can continue to flourish largely unimpeded.

The measure includes clarifying and strengthening existing laws to address risks and harms from AI, through an immediate review of the priority areas of health and aged care sector regulation, the Australian Consumer Law and copyright law.

As part of the Australian Government's Department of Health and Aged Care (the Department), the Therapeutic Goods Administration (TGA) regulates therapeutic goods, including AI models and systems when they meet the definition of a medical device under Section 41BD of the *Therapeutic Goods Act 1989*. The TGA has issued this consultation paper as part of the review of priority areas in the health and aged care sector. The Department is concurrently completing a broader review of the health and aged care regulation and legislation.

This consultation seeks feedback on proposals identified for mitigating risks and leveraging opportunities associated with the use of AI models and systems across our regulated environment, and complements the Department's broader review.

High-risk settings and proposed guardrails

The Department of Industry, Science and Resources (DISR) is leading the whole-of-government Safe and Responsible Use of AI agenda. One proposal is to establish "guardrails" for the development and deployment of AI systems in high-risk settings, while allowing AI use in low-risk settings within the bounds of existing laws.

The proposed principles underpinning the concept of an AI system designated as high-risk due to its use are:

a) The risk of adverse impacts to an individual's rights recognised in Australian human rights law without justification, in addition to Australia's international human rights law obligations

b) The risk of adverse impacts to an individual's physical or mental health or safety

c) The risk of adverse legal effects, defamation or similarly significant effects on an individual

d) The risk of adverse impacts to groups of individuals or collective rights of cultural groups

[1] N Gillespie, S Lockey, C Curtis, J Pool and A Akbari, 'Trust in Artificial Intelligence: A Global Study', *The University of Queensland and KPMG Australia*, 2023, doi:10.14254/00d3c94.

e) The risk of adverse impacts to the broader Australian economy, society, environment and rule of law

f) The severity and extent of those adverse impacts outlined in principles (a) to (e) above.

These principles set a foundation for defining high-risk AI where the proposed uses of an AI system are known or foreseeable. Ten mandatory guardrails are currently proposed for AI models and systems in high-risk settings. The guardrails are intended to place obligations across the AI supply chain and throughout the AI lifecycle to effectively prevent harms before people interact with, or are subject to, an AI system. These obligations are intended to primarily apply to developers and deployers of AI models and systems.

The proposed guardrails are:

- Establish, implement and publish an accountability process including governance, internal capability and a strategy for regulatory compliance.
- Establish and implement a risk management process to identify and mitigate risks.
- Protect AI systems and implement data governance measures to manage data quality and provenance.
- Test AI models and systems to evaluate model performance and monitor the system once deployed.
- Enable human control or intervention in an AI system to achieve meaningful human oversight.
- Inform end-users regarding AI-enabled decisions, interactions with AI and AI-generated content.
- Establish processes for people impacted by AI systems to challenge use or outcomes.
- Be transparent with other organisations across the supply chain of an AI system or model to help them effectively address risks.
- Keep and maintain records to allow third parties to assess compliance with guardrails.
- Undertake conformity assessments to demonstrate and certify compliance with the guardrails.

The DISR consultation on proposals for principles to define high-risk settings, mandatory guardrails that should apply in those settings and options for applying the guardrails is now open.

Please note: while this consultation is not seeking direct feedback on the application of the proposed guardrails in the therapeutic goods sector, proposals outlined below are intended to ensure our legislative and regulatory framework align with the intent of the proposed guardrails. You are encouraged to provide a response directly to the DISR public consultation to specifically address the high-risk settings principles or the impact of proposed mandatory guardrails on therapeutic goods, including medical devices. You can access the DISR public consultation here.

TGA – Legislation review

The TGA is Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods. The TGA regulates therapeutic goods including medicines, medical devices and biologicals to help Australians stay healthy and safe.

Products that meet the legislative definition of a therapeutic good under the *Therapeutic Goods Act 1989* (the Act) are regulated by the TGA. These products generally require pre-market approval and inclusion in the Australian Register of Therapeutic Goods (ARTG) before they can be imported, exported or supplied in Australia.

Adverse events associated with therapeutic goods are likely to have a harmful impact on an individual's physical or mental health and are therefore generally considered to be high-risk under the proposed principles identified above. We therefore consider all AI systems and models within the

therapeutic goods and healthcare sectors will fall within the proposed definition of high-risk as outlined above. We have conducted our review of the current legislative framework for the regulation of these products with the understanding that they are likely to need to demonstrate compliance with the proposed guardrails for high-risk AI models and systems.

The proposals in this paper are intended to ensure our existing legislative framework aligns with the proposed guardrails.

Out of scope

While we recognise the importance of the following areas of regulation, proposals relating to these considerations are not included in the scope of this public consultation as they do not fall within the TGA's legislative remit:

- privacy
- cybersecurity
- clinical practice.

These areas will be explored within the Department's broader review of legislation and regulation. We expect the relevant administrators of these laws will also conduct consultations to identify any potential changes to the legislation to leverage opportunities and mitigate risks across these themes. You are encouraged to provide a response to the broader review which cover health and aged care legislation that do not fall within the TGA's legislative remit.

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 application and operation of the Privacy Act are not a part of the TGA's legislative review.

More information

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 TGA is a part of the Australian Government Department of Health and Aged Care. 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 led by the Australian Signals Directorate's Australian Cyber Security Centre (the Centre). The Centre provides a range of support and advice to stakeholders, including the TGA, with respect to the application of the 2023-2030 Australian Cyber Security Strategy (the Strategy). 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 are not a part of the TGA's legislative review.

More information

Australian cyber security policy is governed by the Australian Cyber Security Centre within the Australian Signals Directorate.

Australia's federal strategy for cyber security - 2023-2030 Australian Cyber Security Strategy.

Clinical and healthcare practice

Clinical and healthcare practice are not regulated by the TGA. This includes where health professionals and practitioners are using AI capability that does not meet the legislative definition of a medical device (for example, virtual assistants for summarising practice notes or managing patient records).

More information

The Australian Health Practitioner Regulation Agency works in partnership with the National 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 leads and coordinates 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.

Scope

The scope of our legislative review incorporates the *Therapeutic Goods Act 1989* 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

To inform this consultation paper, we conducted a series of targeted stakeholder workshops to identify areas of strengths and concerns across the therapeutic goods and healthcare sectors. These workshops were attended by more than 300 individual participants. Information gathered through these workshops included the identification of:

- AI models and systems that are currently used across our regulated environment
- emerging uses of AI models and systems across the regulated environment

- key areas of legislation requiring review.

Participants in the stakeholder workshops included representatives from within the Department of Health and Aged Care, regulatory experts, medical device manufacturers and industry representative bodies, software developers and technical experts, software industry bodies, health care providers, including representatives from professional associations, colleges and primary care physicians, consumer representative bodies, clinical trials and research representatives and the TGA's Technical Reference Group for Software as a Medical Device (SaMD) and Artificial Intelligence (AI).

Feedback from the workshops identified use cases and emerging issues associated with the use of AI models and systems. We have used this information to summarise emerging concerns and shape the questions in this paper. Your response will help further refine our understanding of the potential areas for recommended change.

Broadly speaking the TGA's review of our existing legislation against the guardrails proposed by DISR, coupled with the targeted stakeholder workshops, have identified:

1. Our existing regulatory framework broadly aligns with the proposed guardrails.
2. Some amendments to the existing regulatory framework may be required to ensure all risks and opportunities associated with AI are addressed.

The proposals contained in this consultation seek to ensure:

- Risks associated with AI models and systems in the therapeutic goods sector are appropriately mitigated.
- Opportunities for the use of AI models and systems in the therapeutic goods sector are leveraged without introducing unacceptable levels of risk.
- The regulation of therapeutic goods aligns with the proposed guardrails for use in high-risk settings as far as practicable.

If you wish to provide feedback, you may choose to do so across all the identified issues, or only to those most relevant to you.

The areas identified are:

- Potential changes to the *Therapeutic Goods Act*
- Potential changes to the Medical Devices Regulations
- International alignment and harmonisation
- Transparency
- Review of the software exclusions

Potential changes to the Act

The increasing use of AI models and systems across the regulated environment, as well as the rising number of software products that meet the definition of a medical device, means a review of the language used in legislation, regulations and associated legislative instruments is required. The *Therapeutic Goods Act 1989* (the Act) and subordinate legislation were drafted using definitions and language intended to capture activities in the sector including:

- who is responsible for the manufacture and supply of therapeutic goods
- how therapeutic goods are supplied.

Currently the focus of the Act is centred on activities conducted by human beings. Technological advancements mean many of these activities are increasingly performed by complex algorithms, including AI models and systems.

There are two key potential changes of language and definitions currently in use within the *Therapeutic Goods Act 1989* and subordinate legislation:

1. Potential changes to definitions to further clarify regulatory responsibility where software and products that are, or incorporate, AI models and systems are therapeutic goods.
2. Potential changes to language about activities previously performed by human beings when they are now performed by engineered systems, including AI models and systems.

The following proposals are intended to clarify responsibility for the deployment and use of AI models and systems.

Definitions

While definitions used in the Act may still adequately describe the entities and activities responsible at the appropriate time, stakeholders have indicated potential changes to the definitions would provide clarity and strengthen regulation. Similar language changes have been included in other jurisdictions, including the EU's *AI Act 2024* and Canada's proposed *Artificial Intelligence and Data Act*. Examples of definitions that potentially could be recommended for change include:

- "Supply", to include language about the availability of software products from virtual platforms, for example website or app stores.
- "Manufacturer" to include the appropriate legal entity responsible for the development and deployment of software products that are medical devices.
- "Sponsor" to include a person who provides, hosts, or facilitates access to software products that are medical devices, particularly when they are accessible through data transfer or online platforms only.

Language

AI models and systems have changed the way therapeutic goods are deployed and used. Not only are some medical devices now able to be accessed online, AI models and systems are replacing some services and activities traditionally performed by human beings. Who is responsibility for these activities is an emerging challenge, particularly with continuous learning and generative AI. For example, outputs are not always continuously validated as the system evolves over time, and the original deployer or user of the system may not have sufficient awareness or oversight of the activities the software performs. In other circumstances, a software system may be deployed or configured by an administrator, a medical clinic or health service, but a health professional using the software is not made aware of the performance or limitations of the software.

Clarity is required for who is responsible and liable for the outputs of these systems, particularly when their activities constitute a breach of the Act or other laws. The *Therapeutic Goods Act 1989* (the Act) and subordinate legislation is no exception. Within the Act there are civil and criminal offences including many that are strict liability (where responsibility for an offence is not dependent on the ability to show fault or intent). In addition to a review of definitions to ensure clarity for stakeholders, we are proposing to review the current language used to define responsibility for meeting legal obligations. This will ensure penalties for civil and criminal offences can continue to be applied to the most appropriate legal entity associated with the use of an AI model or system.

Definition and language questions

- Do you broadly agree that a review of the definitions in the *Therapeutic Goods Act 1989* and subordinate legislation is needed to clarify responsibility for the development, deployment and use of AI models and systems?
- Are there specific definitions that should be clarified?

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

  If yes, what are they?

Potential changes to medical device regulation

The TGA regulates AI when it meets the legislative definition of a medical device in Section 41BD of the *Therapeutic Goods Act 1989*. AI products likely to meet this definition include those that are intended to be used for the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of a disease, injury or disability.

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.

Clinical and technical evidence must be available to demonstrate the safety, reliability and performance of the product using AI to the same standard as other medical devices – for higher risk products, clinical and technical evidence requirements are more stringent. For AI products that are regulated as medical devices, feedback from our targeted workshops indicated:

- Australia's current approach to the regulation of medical devices, which relies heavily on international harmonisation, should be maintained.
- The current classification rules and requirements for medical devices are generally sufficient to allow appropriate regulation and adequately mitigate risks associated with AI.
- The current exclusion of some software products may no longer be appropriate, given their increasing complexity and the rising use of AI.

There are three key areas where we are seeking your feedback, including potential changes to the regulation of medical devices that would address the risks associated with the increasing use of AI models and systems:

1. Classification rules
2. Essential principles
3. Software exclusions

Classification rules

Medical devices are regulated based on the risk they pose when used as intended. In Australia the risk posed by a device is determined using "classification rules", where factors impacting the classification of a medical device include:

- Where in the human body the device is intended to be used.

- How long the device is intended to be used continuously.
- Whether the device is intended for use by a consumer or a health professional.
- Whether information is provided for monitoring, or to inform a diagnostic or treatment decision.

The classification rules are detailed in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002. There are specific rules for programmed or programmable medical devices or software that is a medical device which will apply to devices that are, or incorporate, an AI system or model. An extract of Schedule 2 containing these specific rules is at Attachment A.

Classification rules 4.5(1) and 4.5(2)

All AI models and systems that:

- meet the definition of a medical device
- are solely intended to provide a prediction or prognosis for a disease or condition

are currently regulated as Class I medical devices.

AI-enabled devices are increasingly being used to predict clinical outcomes or provide prognostic information about a particular disease or treatment. The existing classification rules do not explicitly account for products intended for prediction or prognosis, meaning a default risk classification of Class I currently applies. This is not considered appropriate in cases where this information is used to determine treatment plans or interventions which could have a significant and detrimental impact on patients if the prediction or prognosis is not accurate.

A potential amendment of the current classification rules 4.5(1) and 4.5(2) to include prediction or prognosis would mean these devices would be classified at a higher level, depending on how serious the disease or condition they are providing information about is and whether the information is being provided to a clinician or a consumer.

Classification rules questions

- Do you agree that programmed or programmable medical devices or software that is a medical device for use in providing a prediction or prognosis in relation to a disease or condition should be reclassified under classification rules 4.5(1) and 4.5(2)? Why or why not?
- Are all other classification rules in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 appropriate for the risks associated with the use of medical devices that are, or incorporate, AI models and systems? Why or why not?
- Should there be specific classification rules for devices that are, or incorporate, AI systems or models? If yes, what are they and why should they be introduced?

The essential principles

The essential principles are safety and performance requirements for all medical devices, including in vitro diagnostic (IVD) devices. These requirements are detailed in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002. 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. 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.

An extract from Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 is at Attachment B. The extract relates to the essential principles most likely to require amendment to address risks associated with medical devices that are, or incorporate, AI models and systems:

- **Essential principle 12.1:** Specific requirements for programmed or programmable medical devices or software that is a medical device.
- **Essential principle 13:** Information to be provided with all medical devices.

Essential principles questions

- Are the current requirements in essential principle 12.1 (Attachment B) sufficient to address the risks emerging from the complexity of the different subtypes of AI?
- Are additional provisions required to address **specific kinds of AI**? (adaptive AI, generative AI, machine learning, etc)

  If yes, what provisions and under which circumstances?
- Should there be additional provisions to ensure the ongoing performance of **open-source** software that is incorporated in medical devices?

  If yes, please provide details.
- Should there be a requirement in the essential principles to identify when **AI is incorporated** in a medical device? (Check all that apply)
  - When it is standalone AI as a medical device.
  - When it is used as part of the device achieving it's 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.
  - Other circumstances (please elaborate).
- Are there other risks associated with the use of AI that should be addressed with additional **labelling requirements**?

  If yes, please provide information about what the risks are and what additional labelling requirements should be introduced.

Software exclusions

In 2021, changes to the Regulations commenced that "carved out" out a number of software-based products from TGA oversight on the basis that:

- they presented a very low risk to users and/or
- they were not medical devices to begin with, and clarity was required for stakeholders and/or
- existing oversight measures were available through other regulatory frameworks to ensure these products were safe and fit for their intended purpose.

These exclusions are detailed in the Therapeutic Goods (Excluded Goods) Determination 2018.

Since 2021 the TGA has been monitoring the exclusions and has received feedback from interested stakeholders, as well as through the targeted workshops that indicate the increasing complexity of some excluded software products and the increasing use of AI mean the exclusions may no longer be appropriate for:

- Consumer health products (Schedule 1, Item 14B)
- Digital mental health tools (Schedule 1, Item 14E)
- Software that is a calculator (Schedule 1, Item 14L)
- Laboratory information management systems (Schedule 1, Item 14O)

Consumer health products

Consumer health products encompasses a wide range of products, both physical and software-based, including:

- wearable fitness monitors for use throughout the day or while exercising
- fitness tracking apps and software-based products that integrate with larger systems or hardware devices like fitness monitors.

Consumer health products are excluded under Schedule 1, Item 14B of the Therapeutic Goods (Excluded Goods) Determination 2018:

> *software, or a combination of software and non-invasive hardware, that is:*
>
> *(a) intended by its manufacturer to be used by a consumer to promote or facilitate general health or wellness by measuring or monitoring (through non-invasive means) a physical parameter, such as movement, sleep, heart rate, heart rhythm, temperature, blood pressure or oxygen saturation; and*
>
> *(b) not intended by its manufacturer to be used:*
>
> *(i) in clinical practice; or*
>
> *(ii) for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a serious disease or a serious condition, ailment or defect*

There are two main issues emerging with the use of the consumer health exclusion:

1. The increasing complexity of software used in health and wellness applications is moving these devices from a general information functionality towards incorporating diagnostic tools.
2. The exclusion is being used to allow the supply of hardware devices including thermometers and blood pressure monitors in circumstances where consumers may believe the product in question is a regulated medical device that can be relied upon for monitoring and managing certain conditions.

Digital mental health tools

Digital mental health tools (DMHTs) include a wide range of products that may be available across multiple platforms. For example:

- apps that provide therapy (e.g. CBT)
- internet-based services
- symptom checkers
- suicide prevention apps.

DMHTs are excluded under Schedule 1, Item 14E of the Therapeutic Goods (Excluded Goods) Determination 2018:

> *software that is a digital mental health tool (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software in a manner that is reviewable by the user*

Exclusion of DMHTs was granted on the basis that an accreditation process for service providers offering these products would be managed by the Australian Commission on Quality and Safety in Health Care (the Commission) via the National Safety and Quality Digital Mental Health Standards (the Standards).

Accreditation to the NSQDMH Standards is voluntary to guide safety and quality in digital mental health care services. Feedback from stakeholders, includes:

- The Standards were not intended to regulate these kinds of therapeutic goods.
- There are safety and performance concerns with a number of these goods.
- Exclusion of these kinds of goods means they are not subject to mandatory requirements for quality, safety and performance.
- An increasing number of goods that do not meet the conditions of the exclusion are entering the market without appropriate oversight.
- Without post-market monitoring or requirements for adverse event reporting, issues with excluded products are not being addressed in a timely manner.
- There is currently no requirement for clinical validation and assessment of technologies incorporated into DMHTs.
- Supply of DMHTs that don't provide a sufficient level of transparency to the end user are entering the market.

Software that is a calculator

Software that are calculators are generally digitised versions of paper-based guides and resources intended to support clinicians and patients (for example, a dosage calculator). Calculators are excluded under Schedule 1, Item 14L of the Therapeutic Goods (Excluded Goods) Determination 2018:

> *software that is a calculator and:*
>
> *(a) either:*
>
> *(i) uses relevant published clinical standards or authoritative sources to make calculations; or*
>
> *(ii) displays calculations and outputs in a manner that may be validated by the user; and*
>
> *(b) is not intended by its manufacturer to control the administration of a calculated dosage*

There are three main issues emerging with the use of the current exclusion:

- Some of these products offer functions beyond a replication of paper-based resources.
- Many of these products are increasingly complex with additional factors incorporated that could not be replicated with paper-based resources.
- A number of them are personalised based on datasets not visible to the users of the products in question.

Laboratory information management systems

Laboratory information management systems are software-based products intended to support the operation of a laboratory. Functionality includes managing samples and associated data. These kinds of systems are excluded in certain circumstances under Schedule 1, Item 14O of the Therapeutic Goods (Excluded Goods) Determination 2018:

> *software that is a laboratory information management system (however named or described) and is not intended by its manufacturer to:*
>
> *(a) manipulate information or data to change, or generate new, diagnostic outputs (other than automating simple calculations or generating report comments); or*
>
> *(b) prevent, monitor, predict, make a prognosis of, treat or alleviate a disease, condition, ailment or defect*

As with other software exclusions, increasing functionality and changes to the way these kinds of products are used mean exclusion may no longer be appropriate.

Potential changes to exclusions

There are two reasons for proposing potential changes to the current exclusions:

1. Where an exclusion has been given for clarity, increasing complexity and technological advancements means these products have evolved and may no longer be a general consumer good and – in many cases – now meet the definition of a medical device and may pose risks to users. Many developers are not recognising this shift and therefore, not seeking regulatory approval.
2. While many of the exclusions would remain appropriate if they were utilised within the original conditions of the exclusion, there is scope creep where the intended purpose of the excluded goods changes over time as functionality becomes available, introducing a higher level of risk for users. Many developers are not recognising this shift and therefore, not seeking regulatory approval.

Potential options for change include:

1. Removing the exclusion for some of these kinds of products and regulating them under the medical device framework.
2. Removing the exclusion of these kinds of products and introducing an exemption for certain products (more information about exemption versus exclusion can be found on the TGA website here).
3. Changing the current conditions of exclusion for these kinds of products.

Exemption of products rather than exclusion provides a pathway to the supply of medical devices with a reduced regulatory burden for sponsors as exempt products are regulated by the TGA but are not required to be included in the ARTG before they are supplied. Advantages of this approach include

the TGA's ability to take post-market action against these kinds of products when they do not meet the requirements for medical devices in terms of demonstrating safety, quality and performance; or where adverse events warrant a recall activity.

Software exclusions questions

- Do you think the existing software exclusions to carve out certain products from the Medical Devices Regulations remain appropriate?
  a. Consumer health products
  b. Digital mental health tools
  c. Software that is a calculator
  d. Laboratory information management systems

  If no, what measures do you consider most appropriate for the identified exclusions? If yes, why?
- Are there other software exclusions you consider inappropriate? If yes, what are they?

International alignment and harmonisation

The challenge of ensuring safe and effective adoption and integration of AI and its associated capabilities is not unique to Australia. Around the world, governments are moving to introduce appropriate legislation and regulations to simultaneously manage risks and leverage opportunities associated with AI capability. The TGA recognises the importance of maintaining international harmonisation in terms of regulatory approaches towards therapeutic goods in order to facilitate access to imported emerging technology by Australian consumers and healthcare professionals, and to support export of products manufactured domestically.

Our proposals therefore:

- consider approaches taken in other jurisdictions
- align with the principles established by the Bletchley Declaration[2] to which Australia is a signatory
- intend to maintain international harmonisation where possible.
- mitigate risks pertinent to the Australian context

More information

The Hiroshima AI Process Code of Conduct.

Frontier AI Safety Commitments: voluntary commitments made by private organisations following the AI Seoul Summit, May 2024.

Canada
Responsible use of artificial intelligence in government.

[2] On 1 November 2023, Australia alongside the EU and 27 countries signed the Bletchley Declaration affirming that AI should be developed, deployed and used in a manner that is safe, human-centric, trustworthy and responsible.

Draft guidance – Pre-market guidance for machine learning-enabled medical devices.

United States
USFDA guidance – Artificial Intelligence and Machine Learning in Software as a Medical Device.

USFDA published list of Artificial Intelligence and Machine Learning (AI/ML) – Enabled Medical Devices.

USFDA – Artificial Intelligence Program: Research on AI/ML-Based Medical Devices.

USFDA – Artificial Intelligence and Machine Learning (AI/ML) for Drug Development.

USFDA – Artificial Intelligence and Machine Learning (AI/ML) for Biological and Other Products Regulated by CBER.

European Union

European AI Strategy.

European Commission – European approach to artificial intelligence.

European Commission – European *AI Act 2024.*

Maintaining international alignment and harmonisation

The TGA is engaged in a number of key international activities, and where possible, seeks to align with approaches taken in other jurisdictions. Our current approach and commitment to international harmonisation is a key element to our regulation of therapeutic goods, allowing 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 in the ARTG. Mutual recognition and the ability to use evidence and certification from comparable overseas regulators streamlines the Australian process for sponsors who are bringing their therapeutic goods to market. These measures ultimately reduce costs and lead times for Australian consumers who are seeking access to therapeutic goods, without introducing unacceptable risks.

Stakeholders have indicated that:

1. international harmonisation of medical device regulation is a key feature underpinning the timely entry of innovative devices to the Australian market
2. failing to maintain international alignment is likely to delay or prevent the supply of some therapeutic goods to the Australian market as the cost of undergoing additional evaluation for entry to such a small market is likely to dissuade sponsors.

International harmonisation questions

- What risks and/or advantages do you see to maintaining international harmonisation?
- Are there circumstances where the risk posed by the use of AI models and systems should override international harmonisation?

Transparency

Transparency has been raised as a consistent issue with the use of AI across all stakeholder groups, particularly consumers and clinicians, who would like to be able to identify the use of AI models and systems more easily. Identifying what transparency about AI use means, and the expectations of different stakeholders, has been difficult because:

- 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
- 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.

Stakeholders have identified there is unlikely to be one approach that would adequately address the need for greater transparency. They have indicated the ability to identify the use of AI is more important where an AI model or system has been used to generate a result or propagate data that may require their review or input to ensure accuracy. For example, where a digital scribe product is suggesting a diagnosis based on the information provided during a consultation with the patient.

The following proposals are based on feedback from stakeholders in the targeted workshops, where they expressed that they are not only seeking information about the use of AI models and systems in the therapeutic goods they have access to – they are also seeking a wide range of information and better links between information held by the TGA and other entities, both public and private.

Stakeholders (including consumers) are seeking information about:

- Whether a therapeutic good has been approved by the TGA.
- What information was used to support the approval to supply a therapeutic good.
- Any special conditions or limitations about the use of a therapeutic good.
- Easy identification of the ARTG inclusion for the therapeutic good, with links to publicly available information such as the product information, consumer medicine information, instructions for use, etc.
- For medical devices that are, or that incorporate AI models and systems – information about, or access to, the datasets that were used to train the AI.

The following proposals are therefore not limited to the identification of AI models and systems either within specific medical devices or therapeutic goods more broadly, but also relate to the kinds of initiatives that could be taken to improve access to information about therapeutic goods:

- Publication of a list of approved medical devices that are, or use, AI on the TGA website, similar to that published by the FDA.
- Use of an identifying symbol or other mark, to show that a therapeutic good has been approved by the TGA.
- The ability to publish the ARTG number on therapeutic goods and to advertise or provide information about the regulatory status of products.
- Identification of devices that use AI within the ARTG public summary.
- Inclusion of product names for therapeutic goods in the ARTG public summary or other publicly accessible database.

Example only

Transparency questions

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

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

  - With a simple mark or symbol that shows that it is "TGA approved".
  - With the ARTG inclusion number.
  - Through a publicly available database.
  - Other (please explain).
- Are there other measures the TGA should implement to improve transparency about the use of AI models and systems in therapeutic goods?

  If yes, what are they?

Guidance, education, information and communication

During the targeted stakeholder workshops, a large number of participants were in agreement that the TGA's existing regulatory framework is already quite robust due to 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.

The TGA has a number of guidance documents and assorted information available on our website to assist stakeholders with understanding how medical devices, including those that are or incorporate AI models and systems, including:

- Clinical evidence guidelines.
- Real World Evidence guidance.
- Is my software regulated? – flow charts and examples to aid with identifying whether a software product is regulated as a medical device and, if so, what regulatory obligations exist.
- How the TGA regulates software based medical devices – detailed information and guidance to aid with identifying whether a software product is regulated as a medical device and, if so, what regulatory obligations exist.
- Excluded software – overview and explanation of currently excluded software.
- Artificial intelligence (AI) and medical device software – information for software /manufacturers about how the TGA regulates AI medical devices.
- Software-based medical devices FAQs – guidance and information answering some of the most frequently asked questions about software-based medical devices.

Guidance, education, information and communication questions

- Is the use of AI models and systems adequately covered by the current guidance and information available on the TGA website?
  If no, what changes or additional material are required?
- Are there places other than the TGA website where information about the regulation of therapeutic goods should be made available?

- Are there specific resources that should be developed to support clinicians and consumers?
  If yes, what are they and where should they be provided?

Next steps

This consultation is an in-principle consultation intended to identify the areas of potential reform or refinement to address the risks and leverage the opportunities associated with the increasing use of AI models and systems in our sector. There are two main outcomes that will arise from this consultation:

1. A report to the Australian Government.
2. Based on a decision and guidance from the government, a potential forward program of work for the TGA which may include further consultation.

Report to government

Our report aims to:

- Identify areas of our legislative and regulatory framework where strengths currently exist and where potential changes could be considered to strengthen the mitigation of risks associated with AI models and systems.
- Raise matters brought up within the consultation that are broader than the TGA's responsibilities, legislation that is interconnected with AI in therapeutic goods and requires cross-agency consideration such as privacy, data security, and cybersecurity.
- Emphasise the importance of international harmonisation being maintained as much as possible to assist access to products and export opportunities.

Attachment A – Classification rules extract

4.5 Programmed or programmable medical device or software that is a medical device for use in relation to diagnosing or screening for a disease or condition

(1) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to:

(a) provide a diagnosis of a disease or condition; or

(b) screen for a disease or condition;

is classified as:

(c) in the case of a disease or condition that:

(i) may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or

(ii) may pose a high risk to public health;

Class III; or

(d) in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (c) does not apply—Class IIb; or

(e) in any other case—Class IIa.

(2) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information to a relevant health professional for the purposes of the health professional making a diagnosis of a disease or condition:

(a) in the case of a disease or condition that:

(i) may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or

(ii) may pose a high risk to public health;

is classified as Class IIb; or

(b) in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (a) does not apply—is classified as Class IIa; or

(c) in any other case—is classified as Class I.

4.6 Programmed or programmable medical device or software that is a medical device for use for monitoring the state or progression of a disease or condition etc.

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information that is to be used for monitoring the state or progression of a disease or condition of a person or the parameters in relation to a person:

(a) in the case where the information to be provided could indicate that the person or another person may be in immediate danger or that there may be a high risk to public health—is classified as Class IIb; or

(b) in the case where the information to be provided could indicate that the person or another person may be in other danger or that there may be a moderate risk to public health—is classified as Class IIa; or

(c) in any other case—is classified as Class I.

4.7 Programmed or programmable medical device or software that is a medical device for use in specifying or recommending treatment or intervention

(1) Subject to subclause (2), a programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to specify or recommend a treatment or intervention:

(a) in the case where the absence of the treatment or intervention or where the treatment or intervention itself:

(i) may lead to the death of a person or a severe deterioration in the state of a person's health; or

(ii) may pose a high risk to public health;

is classified as Class III; or

(b) in the case where the absence of the treatment or intervention or where the treatment or intervention itself:

(i) may otherwise be harmful to a person; or

(ii) may pose a moderate risk to public health;

is classified as Class IIb; or

(c) in any other case—is classified as Class IIa.

(2) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to recommend a treatment or intervention (the ***recommended treatment or intervention***) to a relevant health professional for the purposes of the health professional making a decision about the treatment or intervention:

(a) in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:

(i) may lead to the death of a person or a severe deterioration in the state of a person's health; or

(ii) may pose a high risk to public health;

is classified as Class IIb; or

(b) in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:

(i) may otherwise be harmful to a person; or

(ii) may pose a moderate risk to public health;

is classified as Class IIa; or

(c) in any other case—is classified as Class I.

4.8 Programmed or programmable medical device or software that is a medical device that is to provide therapy to a person through the provision of information

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to provide therapy to a person through the provision of information to the person:

(a) in the case of therapy that may result in the death of the person or a severe deterioration in the state of the person's health—is classified as Class III; or

(b) in the case of therapy that may cause serious harm to the person and where paragraph (a) does not apply—is classified as Class IIb; or

(c) in the case of therapy that may cause harm to the person and where neither paragraph (a) nor (b) applies—is classified as Class IIa; or

(d) in any other case—is classified as Class I.

Attachment B – Essential principles extract

12.1 Programmed or programmable medical device or software that is a medical device

(1) A programmed or programmable medical device, or software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that:

(a) the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; and

(b) any consequent risks, or impairment of performance, associated with one or more fault conditions is eliminated or appropriately reduced; and

(c) the device is resilient with respect to interactions that could occur during the use of the device and that could result in unsafe performance of the device; and

(d) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides suitable warnings in a timely manner:

(i) following the disruption to services upon which the device is dependent for the device's operation; and

(ii) following the performance of the device being adversely affected; and

(e) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides a means by which the user can verify correct operation of the device; and

(f) if relevant to the safety of a patient, or the safety and health of the user or any other person, the integrity and quality of the data or information is maintained; and

(g) if relevant, the privacy of the data or information is maintained.

(2) A programmed or programmable medical device, or software that is a medical device, must be developed, produced and maintained having regard to the generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution).

(3) A programmed or programmable medical device, or software that is a medical device, that is intended to be used in combination with computing platforms must be designed and developed taking into account the capability, resources and configuration of the platforms and the external factors (including information technology environments) related to the use of the platforms.

(4) The manufacturer of a programmed or programmable medical device, or software that is a medical device, must provide instructions or information with the device that sets out requirements (including requirements about hardware, software, information technology environments and security measures) necessary to operate the device as intended.

(5) A programmed or programmable medical device, or software that is a medical device, must be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device, including where appropriate the following:

(a) protection against unauthorised access, unauthorised influence or unauthorised manipulation;

(b) minimisation of risks associated with known cybersecurity vulnerabilities (including either or both of remediation of known vulnerabilities and application of compensating controls);

(c) facilitation of the application of updates, patches, compensating controls and other improvements;

(d) disclosure of known vulnerabilities in the device or its components and associated mitigations;

(e) making available sufficient information for a user to make decisions with respect to the safety of applying, or not applying, updates, patches, compensating controls and other improvements.

(6) The manufacturer of a programmed or programmable medical device, or software that is a medical device, having regard to the intended purpose of the device, the generally acknowledged state of the art and best practice, must ensure that the data that influences the performance of the device is:

(a) representative; and

(b) of sufficient quality; and

(c) maintained to ensure integrity; and

(d) managed to reduce bias

13 Information to be provided with medical devices

13.1 Information to be provided with medical devices—general

(1) The following information must be provided with a medical device:

(a) information identifying the device;

(b) information identifying the manufacturer of the device;

(c) information explaining how to use the device safely;

having regard to the training and knowledge of potential users of the device.

(2) In particular:

(a) the information required by clause 13.3 must be provided with a medical device; and

(b) if instructions for use of the device are required under subclause 13.4, the information mentioned in subclause 13.4(3) must be provided in those instructions.

(3) The information:

(a) must be provided in English; and

(b) may also be provided in any other language.

Note: The information may also include diagrams or drawings.

(4) The format, content and location of the information must be appropriate for the device and its intended purpose.

(5) Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimetre high.

(6) If a symbol or identification colour that is not included in a medical device standard is used in the information provided with the device, or in the instructions for use of the device, the meaning of the symbol or identification colour must be explained in the information provided with the device or the instructions for use of the device.

13.2 Information to be provided with medical devices—location

(1) Unless it is impracticable or inappropriate to do so, the information required to be provided with a medical device must be provided on the device itself.

(2) If it is not practicable to comply with subclause (1) in relation to the provision of the information, the information must be provided:

(a) on the packaging used for the device; or

(b) in the case of devices that are packaged together because individual packaging of the devices for supply is not practicable—on the outer packaging used for the devices.

(3) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under subregulation 10.2(1) or clause 13.3:

(a) for a medical device that is not software—the information must be provided on a leaflet supplied with the device; or

(b) for a medical device that is software—the information must be provided on a leaflet supplied with the device or the information must be provided electronically.

(4) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under clause 13.4, the information must be provided in a printed document or using other appropriate media.

13.3 Information to be provided with medical devices—particular requirements

The information mentioned in the following table must be provided with a medical device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)
3	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
4	Any particular handling or storage requirements applying to the device
5	Any warnings, restrictions, or precautions that should be taken, in relation to use of the device
6	Any special operating instructions for the use of the device
7	If applicable, an indication that the device is intended for a single use only
8	If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
9	If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device—the device is intended for performance evaluation only
10	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
11	The batch code, lot number or serial number of the device
12	If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used
13	If the information provided with the device does not include the information mentioned in item 12—a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device, provided the date is clearly identifiable)
14	If applicable, the words 'for export only'

Note: In addition to the information mentioned in the above table, regulation 10.2 requires certain information to be provided with a medical device.

13.4 Instructions for use

(1) Instructions for the use of a medical device must be provided with the device.

(2) However, instructions for the use of a medical device need not be provided with the device, or may be abbreviated, if:

(a) the device is a Class I medical device, a Class IIa medical device or a Class 1 IVD medical device; and

(b) the device can be used safely for its intended purpose without instructions.

(3) Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used
3	Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices)
4	Information about the intended performance of the device and any undesirable side effects caused by use of the device
5	Any contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device
6	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
7	Any particular handling or storage requirements applying to the device
8	If applicable, an indication that the device is intended for a single use only
9	If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
10	If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device—the device is intended for performance evaluation only
11	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
12	For a device that is intended by the manufacturer to be supplied in a sterile state: (a) an indication that the device is sterile; and (b) information about what to do if sterile packaging is damaged; and (c) if appropriate, instructions for resterilisation of the device
13	For a medical device that is intended by the manufacturer to be sterilised before use—instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles
14	Any special operating instructions for the use of the device
15	Information to enable the user to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the device operates properly and safely during its intended life
16	Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life
17	Information about any treatment or handling needed before the device can be used
18	For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose—sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination
19	For an implantable medical device—information about any risks associated with its implantation

Item	Information to be provided
20	For a reusable device: (a) information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilisation of the device); and (b) an indication of the number of times the device may be safely reused
21	For a medical device that is intended by the manufacturer to emit radiation for medical purposes—details of the nature, type, intensity and distribution of the radiation emitted
22	Information about precautions that should be taken by a patient and the user if the performance of the device changes
23	Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions
24	Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device
25	Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device
25A	For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device
26	Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device
27	Information about the degree of accuracy claimed if the device has a measuring function
28	Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device
29	For an IVD medical device, information (including, to the extent practicable, drawings and diagrams) about the following: (a) the scientific principle (the 'test principle') on which the performance of the IVD medical device relies; (b) specimen type, collection, handling and preparation; (c) reagent description and any limitations (for example, use with a dedicated instrument only); (d) assay procedure including calculations and interpretation of results; (e) interfering substances and their effect on the performance of the assay; (f) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision; (g) clinical performance characteristics, such as sensitivity and specificity; (h) reference intervals, if appropriate; (i) any precautions to be taken in relation to substances or materials that present a risk of infection
30	For an adaptable medical device, instructions for assembling or adapting the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles
31	For a medical device production system, instructions for the process to be followed in producing the medical device the system is intended to produce which, if followed, will ensure that the device so produced will comply with the applicable provisions of the essential principles

13A Patient information about implantable medical devices or active implantable medical devices to be made available

13A.1 Scope of clauses 13A.2 to 13A.4

(1) Clauses 13A.2 to 13A.4 apply to a medical device that is:

(a) an implantable medical device or an active implantable medical device; and

(b) not a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector or similar article; and

(ba) not intended by the manufacturer to be for export only; and

(c) not a medical device to which subclause (2) applies.

(2) This subclause applies to a medical device if:

(a) the medical device is intended by the manufacturer to be wholly, or mostly, absorbed by a patient's body within 6 months of being implanted; and

(b) the medical device is:

(i) for use as a filler; or

(ii) for haemostasis; or

(iii) for tissue approximation; or

(iv) for the fixation of other medical devices within tissue; or

(v) a similar medical device to a medical device covered by subparagraph (i), (ii), (iii) or (iv).

13A.2 Patient implant cards etc. for implantable devices

(1) Either:

(a) a card (a patient implant card) that includes the information covered by subclause (2) and that satisfies clause 13A.4 must be made available for provision to the patient concerned; or

(b) information covered by subclause (2) that is in electronic form and that satisfies clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.

(2) The information covered by this subclause is the information in the following table.

Information to be made available for provision to patient

Item	Information
1	(a) the name of the device; and (b) the model of the device; and (c) the batch code, lot number or serial number of the device
2	The manufacturer's name, address and website

13A.3 Patient information leaflets etc. for implantable devices

(1) Either:

(a) a leaflet (a ***patient information leaflet***) that includes the information covered by subclauses (2) and (3) and that satisfies subclause (4) and clause 13A.4 must be made available for provision to the patient concerned; or

(b) information covered by subclauses (2) and (3) that is in electronic form and that satisfies subclause (4) and clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.

(2) The information covered by this subclause is the following information:

(a) information identifying the device, or the kind of device;

(b) the intended purpose of the device;

(c) information explaining how to use the device safely;

(d) other information about the device that the manufacturer considers would be useful for patients.

(3) The information covered by this subclause is the information in the following table.

Information to be made available for provision to patient	
Item	**Information**
1	(a) the name of the device; and (b) the model of the device
2	(a) the intended purpose of the device; and (b) the kind of patient on whom the device is intended to be used
3	Any special operating instructions for the use of the device
4	(a) the intended performance of the device; and (b) any undesirable side effects that could be caused by use of the device
5	Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2)
6	(a) warnings about risks that could arise from the interaction of the device with other equipment; and (b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional Example 1: The risk of electrical interference from electro-surgical devices. Example 2: The risk of magnetic field interference from magnetic resonance imaging devices.
7	(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and (b) symptoms that could indicate that the device is malfunctioning; and (c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and (d) the expected device lifetime; and (e) anything that could shorten or lengthen the device lifetime; and (f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and (g) other circumstances in which the patient should contact a health professional in relation to the operation of the device
8	(a) the materials and substances included in the device; and (b) any manufacturing residuals that could pose a risk to the patient
9	(a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and (b) the address of the Therapeutic Goods Administration's website

(4) The information covered by subclauses (2) and (3) must be written in a way that is readily understood by patients.

13A.4 General requirements for information to be made available for patients

(1) The information covered by subclause 13A.2(2) or 13A.3(2) or (3):

(a) must be included in English; and

(b) may also be included in any other language.

Note: The information may also include diagrams or drawings.

(2) Any number, letter or symbol, or letter or number in a symbol, that is part of the information covered by subclause 13A.2(2) or 13A.3(2) or (3) must be:

(a) legible; and

(b) if the number, letter or symbol, or letter or number in a symbol, is included in a patient implant card or patient information leaflet—at least 1 millimetre high.

13B Software—version numbers and build numbers

(1) For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device.

(2) The current version number and current build number of the software:

(a) must be in English; and

(b) may also be in any other language.

Attachment C – Definitions

The following definitions are provided to assist in your understanding of the concepts and terminology used in this consultation paper or that may be included in your submission to the consultation.

Artificial Intelligence (AI) system: a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment.[3]

Artificial Intelligence (AI) system and model[4]:

- ***AI model:*** the raw, mathematical essence that is often the 'engine' of AI applications.
- ***AI system:*** the ensemble of several components, including one or more AI models, that is designed to be particularly useful to humans in some way.

  For example, the ChatGPT app is an AI system. Its core engine, GPT-4, is an AI model.

AI lifecycle: All events and processes that relate to an AI system's lifespan. This spans from inception to decommissioning, including its design, research, model development, training, deployment, integration, operation, maintenance, sale, use, and governance.

AI supply chain: the complex network of actors and organisations that enable the use and supply of AI throughout the AI lifecycle from model design, testing and fine tuning to deployment and integration into the local IT system.

General-purpose AI (GPAI): a type of AI system or model that addresses a broad range of tasks and uses, both intended and unintended by developers.

Generative AI model: an AI model with the capability of learning to generate content such as images, text, and other media with similar properties to its training data.

LLMs: Large language models are 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 algorithms to improve performance at a task based on data. Real-world examples of AI and machine learning technologies include[5]:

- *An imaging system that uses algorithms to give diagnostic information for skin cancer in patients.*
- *A smart sensor device that estimates the probability of a heart attack.*

Narrow AI system: a type of AI system or model that is focused on defined tasks and uses 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.

Deployer: Any individual or organisation that supplies or uses an AI system to provide a product or service. Deployment can be 'internal', where a system is only used by the developers, or 'external', allowing the public or other non-developer entities to use it.

Developer: Organisations or individuals who design, build, train, adapt, or combine AI models and applications.

[3] Organisation for Economic Co-operation and Development (OECD), What is AI? Can you make a clear distinction between AI and non-AI systems? OECD, 2024, accessed 8 May 2024.

[4] *International Scientific Report on Safety of Advanced AI: Interim Report (2024),* p 16.

[5] U.S. Food & Drug Administration (USFDA), Artificial Intelligence and Machine Learning in Software as a Medical Device, 2024, accessed 8 May 2024.

End user: Any intended or actual individual or organisation that consumes an AI-based product or service, interacts with it or is impacted by it after it is deployed.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Section/Office	XX/XX/XXXX or Month Year

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