Software and AI compliance and reforms

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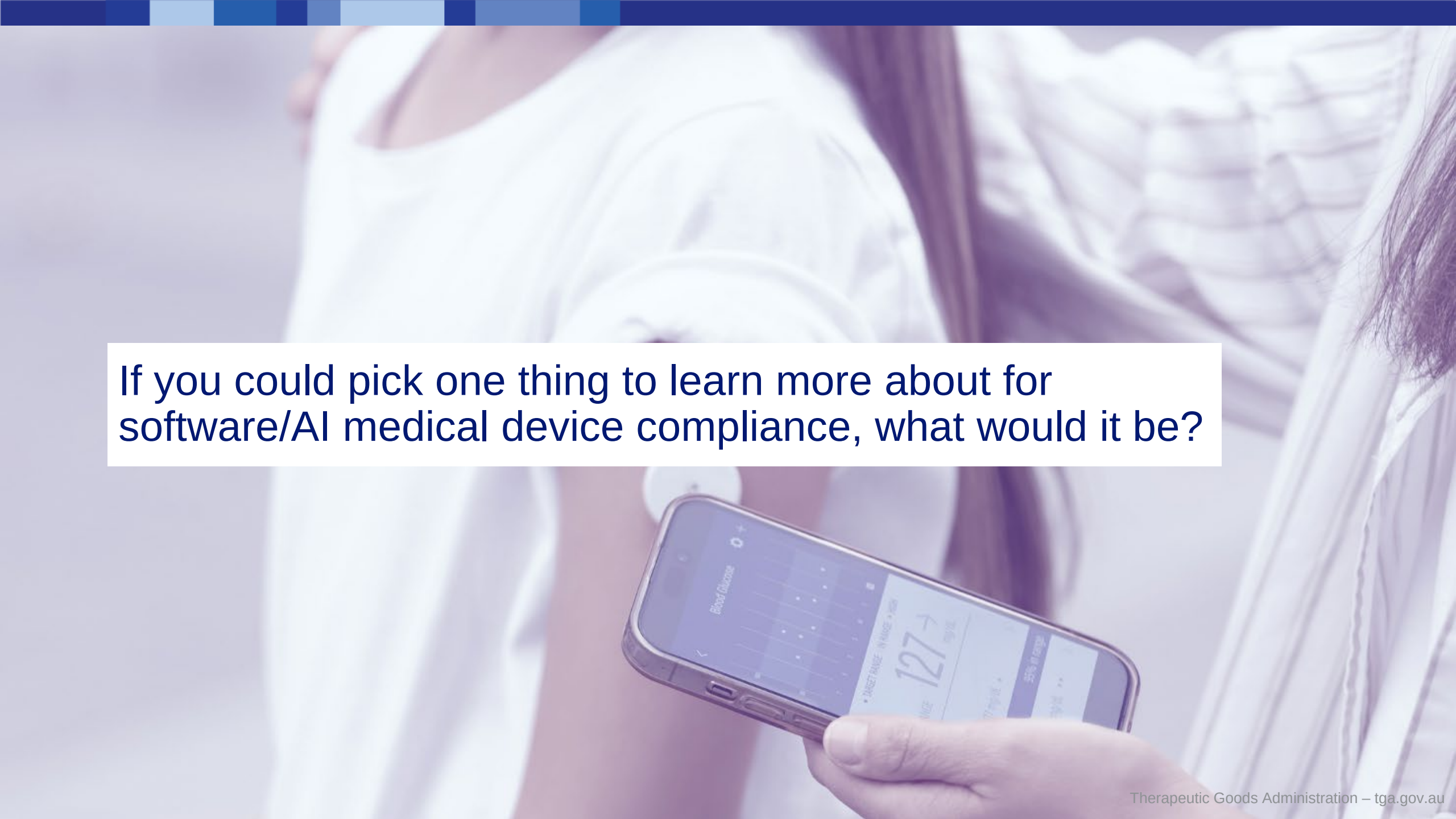
Department of Health, Disability and Ageing, TGA

Session overview

- Overview of AI in health
- Update on the TGA's AI Review
- Software compliance review progress

Key learning outcomes

- Identify the key themes that were raised in the 2024 AI Review.
- Gain awareness of ongoing and upcoming work and how you can provide input/feedback.
- Understand when a digital scribe becomes a medical device.
- Know who to contact and how for more information about software of AI medical devices



If you could pick one thing to learn more about for software/AI medical device compliance, what would it be?

When is software (including AI) a medical device?

Manufacturer’s intended purpose is critical

Software is a medical device when the **manufacturer *intends*** for their product to be used for:

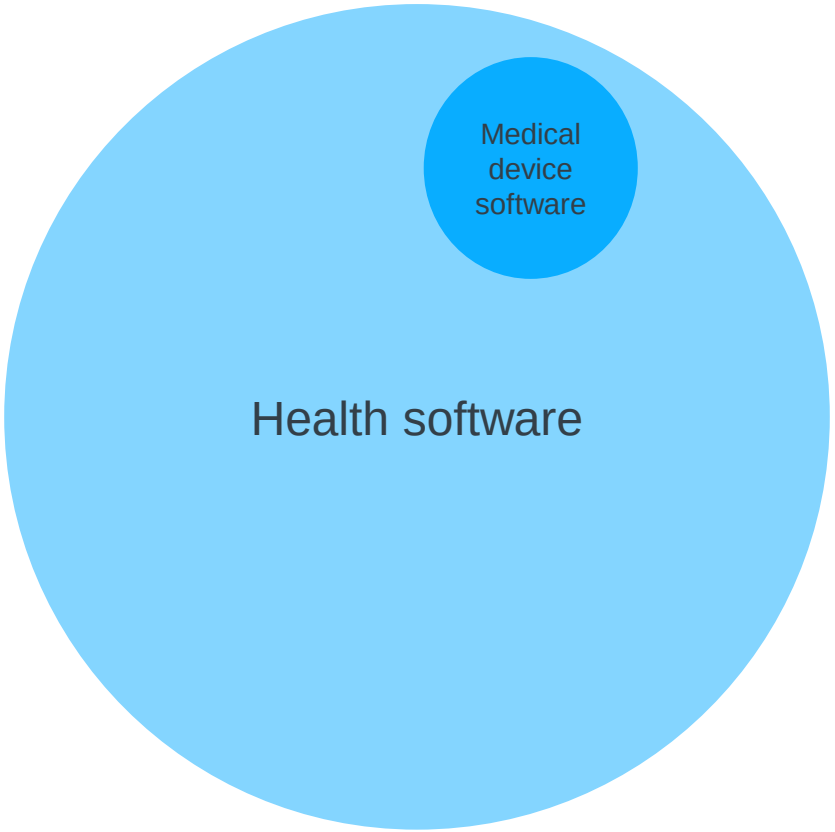
- diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury or disability
- compensation for an injury or disability
- investigation of the anatomy or of a physiological process
- to control conception

Software that is an **accessory** to another medical device.

What TGA doesn’t regulate

We don’t regulate:

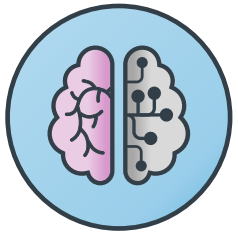
- Consumer products (not for therapeutic use)
- Well-being software
- Privacy (unless it is relevant to safety or performance of a medical device)
- Clinical practice
- Re-imbursement



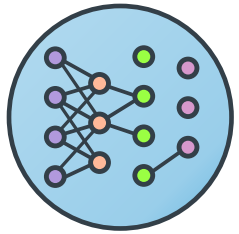
What is artificial intelligence (AI)?

AI is a subset of software that can mimic human capabilities including:

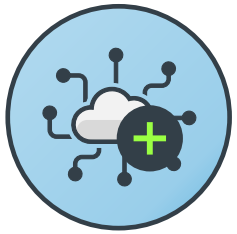
- understanding language
- recognising objects and sounds
- learning and problem solving



Machine learning (ML)

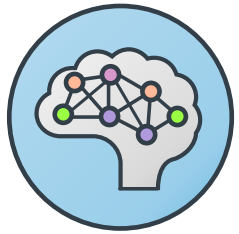


Deep learning

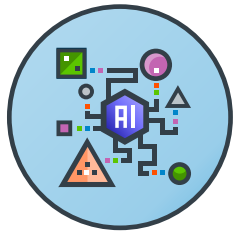


Generative AI

Large language models (LLM)



Neural networks



Adaptive AI

AI use cases in healthcare settings

Diagnostics

Analysing medical images and genomic data

Aid in identifying anomalies or diseases

Predictive analytics

Identifying at-risk patients for conditions (including chronic diseases, sepsis, etc.) readmissions, and adverse drug events

Improving patient care and outcomes while reducing costs

Drug discovery

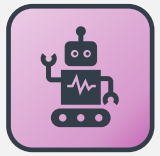
Analysing datasets to identify potential drug candidates

Reducing the lead time to treatment and potentially leading to faster availability of new medications

EHR system integration

Managing patient data, automating administrative tasks, and improving decision-making by providing relevant patient information

Reducing administrative errors, improving patient outcomes



Virtual assistants

Constant patient monitoring, preventative analytics, early intervention, medication management, companionship and mental health support

Better outcomes for long-term and chronic conditions

AI – regulation, policy and oversight

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

Australian Government
Office of the Australian Information Commissioner

Australian Commission on Safety and Quality in Health Care

ASD AUSTRALIAN SIGNALS DIRECTORATE
ACSC Australian Cyber Security Centre

Ahpra & National Boards

ACCC AUSTRALIAN COMPETITION & CONSUMER COMMISSION

ACT Government

NORTHERN TERRITORY GOVERNMENT

Government of South Australia

VICTORIA State Government

NSW GOVERNMENT

Queensland Government

Tasmanian Government

GOVERNMENT OF WESTERN AUSTRALIA

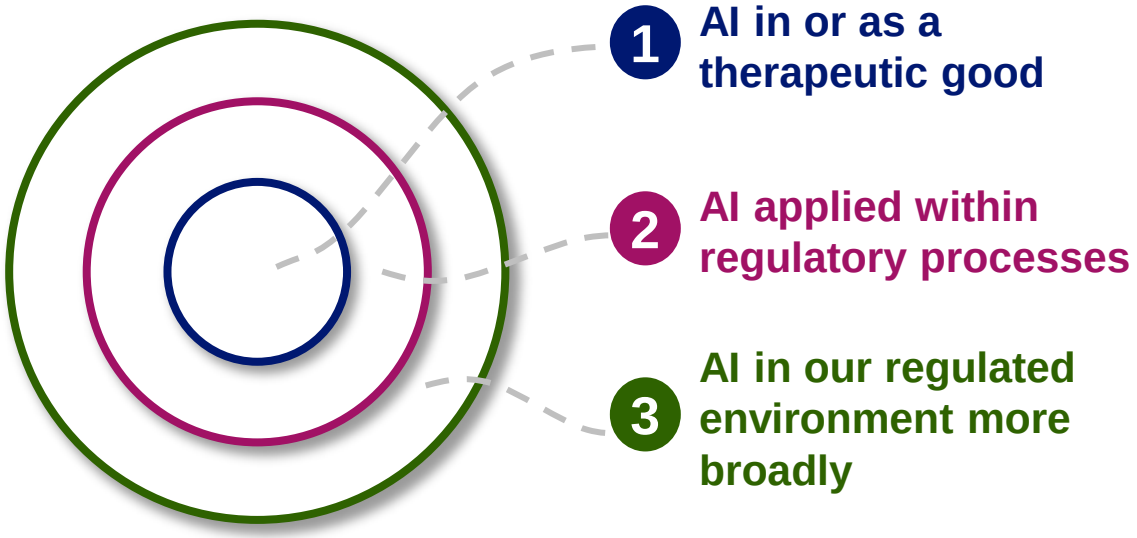
Why regulate AI?

- Need confidence that apps work consistently
  - Analytical and clinical performance, consistent results
- Risk of poor performance for software is just as great than for physical devices, and
  - Software developers have not done as thorough clinical testing as for physical devices
  - There is more limited information in the refereed literature on clinical or analytical validation
- While software apps are improving, there are several examples of products incorrectly diagnosing or monitoring serious conditions e.g. melanoma, arrhythmia or diabetes
- Anecdotal evidence that generative AI is producing inaccurate medical material

SaMD and AI Regulation – TGA legislative review

How prepared are we for the rising use of AI? Is our SaMD framework still fit for purpose?

- How well does our framework align with the intent of the Government's proposed AI guardrails?
- What changes, if any, do we need to make to our framework to ensure the safe and responsible use SaMD and AI models and systems in our regulated environment? Are the exemptions and exclusions still appropriate?
- What guidance and education is required?



Targeted stakeholder consultation — Complete

Public consultation — Closed 20 Oct 2024

Report to government — Delivered Dec 2024

Forward work plan — Ongoing

AI regulation – TGA consultation themes

Potential changes to the Act

Definitions and language updated to clarify responsibility and appropriately capture activities that are now performed by systems

Transparency

A broad term which means different things to different people.

Understanding occurs across a spectrum and transparency will need a multi-faceted approach

Potential changes to medical device regulation

Our technology-agnostic framework is largely fit for purpose. Minor amendments may be needed to ensure risks associated with AI are mitigated

Guidance, education, information and communication

What information do people need?

Where do they need to be able to find it?

International alignment and harmonisation

Our framework harmonises with other jurisdictions as much as possible.

Is our approach appropriate?

Legislative review and stakeholder consultation approach

5 WORKSHOPS WITH INTERNAL TGA STAKEHOLDERS

Internal TGA engagement

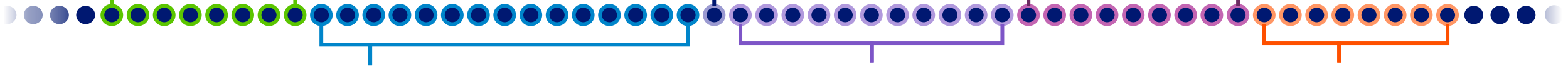
2 JOINT WEBINARS WITH DISR

148 PARTICIPANTS

Collaboration

2300+ INDIVIDUAL COMMENTS

Analysis & synthesis



Targeted stakeholder engagement

14 TARGETED WORKSHOPS

305 PARTICIPANTS

Public consultation

2 PUBLIC WEBINARS WITH **217** PARTICIPANTS

53 FORMAL RESPONSES

Report

14 FINDINGS ACROSS FIVE PRIORITY AREAS

TGA AI Review report – Clarifying and strengthening the regulation of Medical Device Software including AI

Overview of key findings

While our **existing framework and approach is largely fit for purpose (91%)**, stakeholders need more support to meet existing requirements

Minor changes are needed to ensure the framework continues to be appropriate

More **transparency, education** and **communication** is needed for all stakeholders

A **multi-faceted approach** is needed to achieve these outcomes

AI use is rapidly evolving and accelerating, **strong collaboration and engagement** will be needed to support ongoing review and refinement

SaMD and AI Regulation Review – Outcomes

Five strategic priority areas emerged from the Review – commenced work on these

Priority Area 1 **Supporting stakeholders**	Providing clear information and guidance explaining regulatory requirements to support compliance.	• Multiple channels for communication • Targeted support for specific sectors
Priority Area 2 **Robust regulation**	Refining regulation to ensure risks associated with therapeutic goods continue to be appropriately mitigated throughout their lifecyc	• Medical Devices Regulations 2002 • Excluded Goods Determination 2018 • Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Priority Area 3 **Reinforce roles & responsibilities**	Ensuring language in our legislative framework (the Act) captures responsibility appropriately	• Mapping emerging terminology to existing definitions • Introducing new definitions where needed
Priority Area 4 **Improve transparency of AI use**	Facilitating access to information and support for stakeholders to understand how AI is used the goods they access and how it is regulated.	• Explore levers for improving transparency of AI use
Priority Area 5 **Conducting compliance**	Pragmatic and timely compliance activities to ensure the policy outcomes	• Ongoing compliance

Priority Area 1

Supporting stakeholders

What we heard

- 78% of respondents said AI-related information on the TGA website is inadequate
- The TGA website is not well organised or easily searchable
- More work is needed to help stakeholders access information
- Specific content and landing pages for consumers should be considered
- Current regulatory requirements should be better articulated

Work packages
Review and refinement of the TGA website structure and content
Ongoing monitoring & refinement

Providing clear information and guidance explaining regulatory requirements

- Uplift of information on TGA website – Updated architecture, easily searchable
- Targeted support for specific sectors – new guidance developed (digital scribes, AI and medical device software regulation, Software-based medical devices for health professionals)
- Ongoing webinars, stakeholder engagement to provide information for industry about software and AI regulation

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Ongoing…

- **ANDHealth webinars** for industry and developers new to regulation about requirements for software and AI
- **Other** direct industry engagement to provide education and training, e.g. through MTAA and MSIA
- **One-on-one regulatory engagement meetings with developers** to:
  - understand the product and the appropriate regulatory requirements (e.g. classification)
  - Determine what is needed for market authorisation and identify any key issues to resolve

Priority Area 2

Robust regulation

What we heard

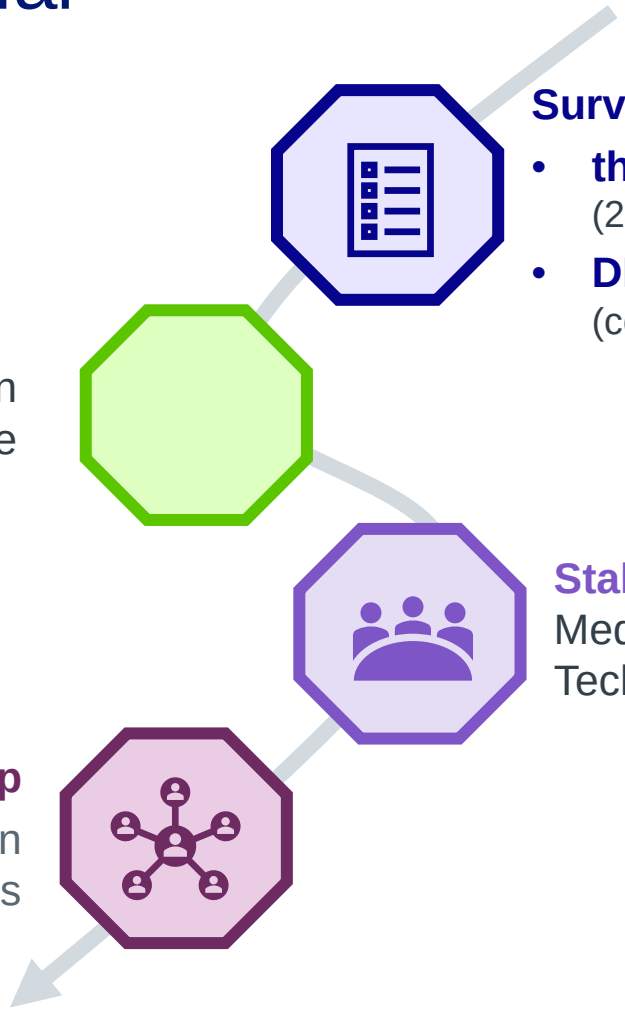
- Refinements to address risks will be needed as new devices enter the market
- We should continue to review our approach as standards and guidelines are developed
- 62% of respondents said that the conditional exclusion of Digital Mental Health Tools is **no longer appropriate**

Work packages
Further review of the Excluded Goods Determination 2018
Public consultation

Review of Digital Mental Health Tool (DMHT) exclusion

- Stakeholders, including consumers and health professionals, have called for **urgent review** of the DMHTs exclusion due to concerns of misuse
- The existing DMHT exclusion (2021) was intended to avoid duplicating requirements anticipated under the Australian Commission on Safety and Quality in Healthcare (ACSQHC) national Standards
    - The NDMH Standards are voluntary and apply to the delivery of services, not products
    - Only a few DMHTs have been identified that meet all exclusion criteria
- Stakeholders continue to believe the exclusion is applicable to all DMHTs

Key activities so far



Surveys of:

- **the DMHT regulatory environment**
  (24 responses)
- **DMHT users**
  (consumers - 42 responses; professional users - 79 responses)

Market research on
consumer-facing health software

Stakeholder engagement via
Medical Devices Consumer Working Group;
Technical Reference Group for SaMD and AI

Establishment of DMHTs Expert Group

20 members; TGA has hosted an
introductory meeting + 3 workshops

DMHT exclusion review

Research, lead work…

- **DMHT regulatory environmental survey** – developers, deployers, suppliers
- **DMHTs user survey responses** – consumers, professional users
- **ORIMA market research** on consumer-facing health software
- **Feedback from stakeholders** in meetings – Medical Devices Consumer Working Group, Technical Reference Group for SaMD and AI
- **Established the DMHTs Expert Group** (DMHT-EG) to facilitate information sharing and expert discussion between the TGA and invited experts – 20 members, TGA has hosted an introductory meeting + 3 workshops

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Upcoming…

- **Continue to work with DMHT-EG and affected stakeholders**
  - **Develop potential options** for modification or removal of existing exclusion for DMHTs for public consultation
  - Requires detailed engagement with DMHT-EG, Mental Health & Suicide Prevention Division (MHSPD), Regulatory Legal Services Division (RLSD), Office of Impact Analysis (OIA), Australian Commission on Safety and Quality in Healthcare (ACSQHC)

Priority Area 3

Reinforce roles & responsibilities

What we heard

Software developers and health professionals don’t identify with the definitions used in our legislation

Clarity is required to establish regulatory responsibilities are assigned to the right people

Regulation needs to capture new practices appropriately (software making decisions instead of clinicians, for example)

Work package
Mapping emerging terminology to existing definitions
Public consultation to introduce/amend definitions as required

Review of legislated definitions

- Emerging terminology and definitions used across the lifecycle of software products are not currently used in the legislation, or they may not align with those used in software sector or clinical practice
- Terms include **Manufacturer/Developer; Sponsor; Distributor/Deployer; User; Supply**
  - Clarity is required for who is responsible for the outputs of these systems, particularly when their activities constitute a breach of the Act or other laws
  - Clarity is needed for other definitions and terms when specifically applied to software

Priority Area 4

Improve transparency of AI use

What we heard

- 69% of respondents want to be able to identify when therapeutic goods have been “TGA approved”
- Respondents proposed new initiatives including:
  - use of QR codes to take stakeholders to more information about a therapeutic good
  - identification of devices that are, or incorporate, AI in a publicly available list or the ARTG summary
  - inclusion of trade and model names in the ARTG public summary

Work package
Review and refinement of therapeutic goods advertising and labelling requirements
Public consultation

Transparency of SaMD and AI-based medical devices

Commenced…

- **Publish list** of AI in the ARTG
- **Engage with platform providers** to explore if transparency measures adopted in EU/USA/UK can be implemented in Australia
  - Includes processes to require certain categories of software to provide further information
  - Segregation of SaMD, with requirement to include details of intended use, regulatory status
  - Potential to include:
    - Ability for users to report safety issues of health-related products
    - Better reporting mechanisms for non-compliant products (e.g. to facilitate rapid takedown)

Priority Area 5

Conducting compliance

What we heard and what we're doing…

Education and communication need to be paired with compliance activities

Review of products like digital scribes is needed to determine whether/when they are medical devices

Work packages
Ongoing direct engagement with the software sector for educative purposes
Development of additional guidance and information
Targeted compliance action to remove non-compliant devices from supply

Compliance activities

Focus on compliance of AI and software-based medical devices

We are already working closely with industry to:

- encourage voluntary compliance
- provide clear and consistent guidance
- respond to complaints and reports of non-compliance
- identify and address unlawful advertising and supply.

Digital Scribe Review

- **Scoping** – research to identify suppliers and functionality of digital scribes in Australia.
- **Education** – improve industry understanding of regulatory obligations.
- **Review** – we requested information (voluntary) to see if digital scribes in Australia meet the definition of a medical device; we are reviewing the responses; several developers have met with us and engaged proactively

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Upcoming…

- Chatbot review
- Systematic review of Clinical Decision Support System (CDSS) software, notified as exempt

Why a strategy for unlawful supply of SaMD?

End of the transition period for software

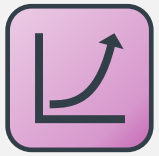
Exemptions and exclusions

New classification rules

Amended Essential Principles

2024-2025 Budget measure

Safe and Responsible AI to ensure **safe deployment in high-risk** settings while allowing innovation in low-risk areas



Rapid growth

Huge increase in availability of SaMD utilizing AI/ML

Has the potential to impact a lot of people due to its accessibility

Non-compliance

Many SaMD remain non-compliant despite extended transition periods and education.

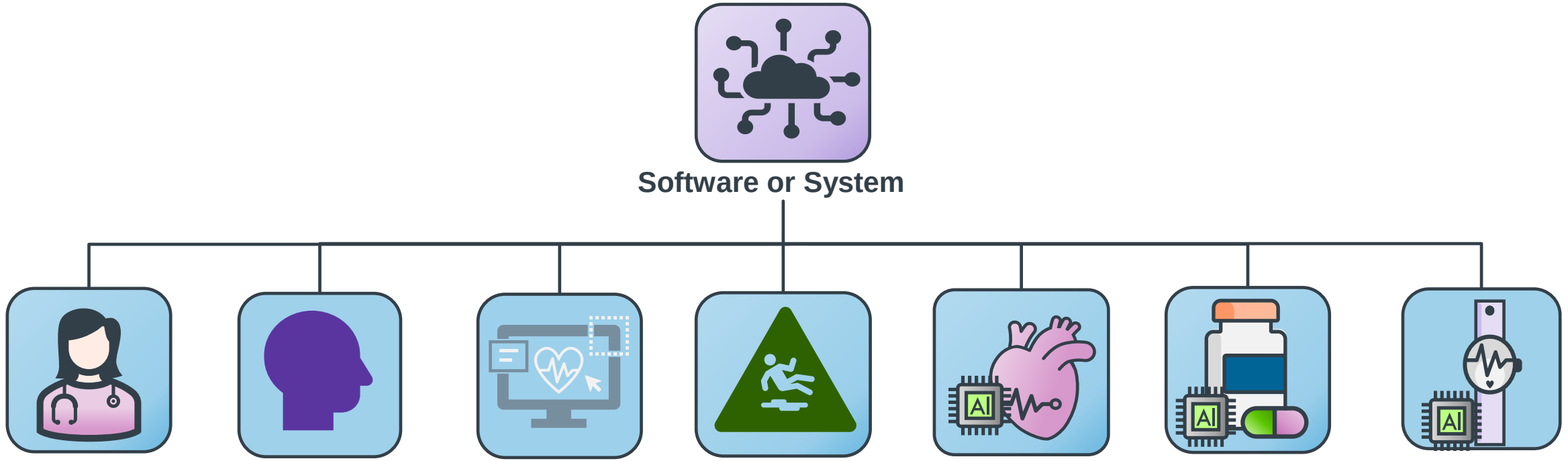
Risks

Risks are amplified by AI due to the potential for biased data,
opaque outputs
model drift.

Public trust

Public trust in AI is low.
Lots of uncertainty.
Expectation is that “someone is checking”

What are high-risk settings?



Inform, drive or replace clinical decisions

Provide therapy directly to an individual

Used in critical healthcare settings

Could cause significant harm if malfunctioned

Diagnose or predict disease progression

Recommend or administer treatment

Monitor vital sign or detect emergencies

Compliance and enforcement actions available to the TGA

The regulatory ‘tools’ can be used individually or in combination

Risk prioritisation considers:

- Severity of harm
- Number of affected consumers
- Public/media interest
- Compliance history
- Activities will focus on voluntary and assisted compliance, and escalation if necessary

What are digital scribes?

Digital scribes

Being used in clinical settings to:

- Capture conversations with patients
- Generate clinical notes
- Create summaries
- Prepare letters

The information created is added to a patient's record.

Regulatory requirements

May need to comply with:

- Privacy Act 1988
- Cyber Security Act 2024
- National Registration and Accreditation Scheme (Ahpra)
- Australian Consumer Law
- Pragmatic AI guidance for clinicians (ACSQHC)

Not a medical device

Digital scribes

Additional features, such as:

- Perform analysis and interpretation of clinical conversation
- Generating diagnosis or treatment options **not explicitly stated by the HCP**

Regulatory requirements

Additional requirements:

- Meet all relevant Essential Principles
- Be included in the ARTG before being supplied

Is a medical device

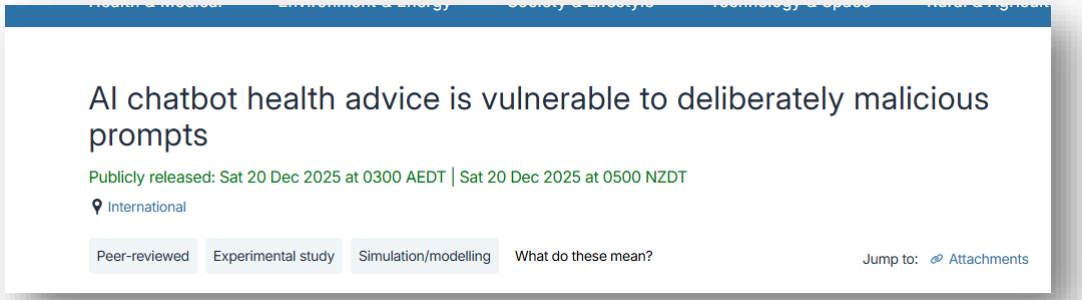
Boundaries – Digital scribes

- Generates a written record of clinical conversations for clinician review
- Applies basic editorial changes to improve grammar or standardise language
- Summarises clinical discussions for the purposes of clinician review

- Generates information not stated/discussed during a consultation regarding:
  - Diagnosis
  - Differential diagnosis
  - Treatment or intervention recommendations
  - Prediction or prognosis

Manufacturers must continuously monitor for functionality that may meet the definition of a medical device

Health Chatbots



AI chatbot health advice is vulnerable to deliberately malicious prompts

Publicly released: Sat 20 Dec 2025 at 0300 AEDT | Sat 20 Dec 2025 at 0500 NZDT

International

Peer-reviewed | Experimental study | Simulation/modelling | What do these mean? | Jump to: Attachments

What happened when we tested a 'safe' AI mental health chatbot

By the Specialist Reporting Team's Paige Cockburn

Mental Health

Tue 30 Dec 2025

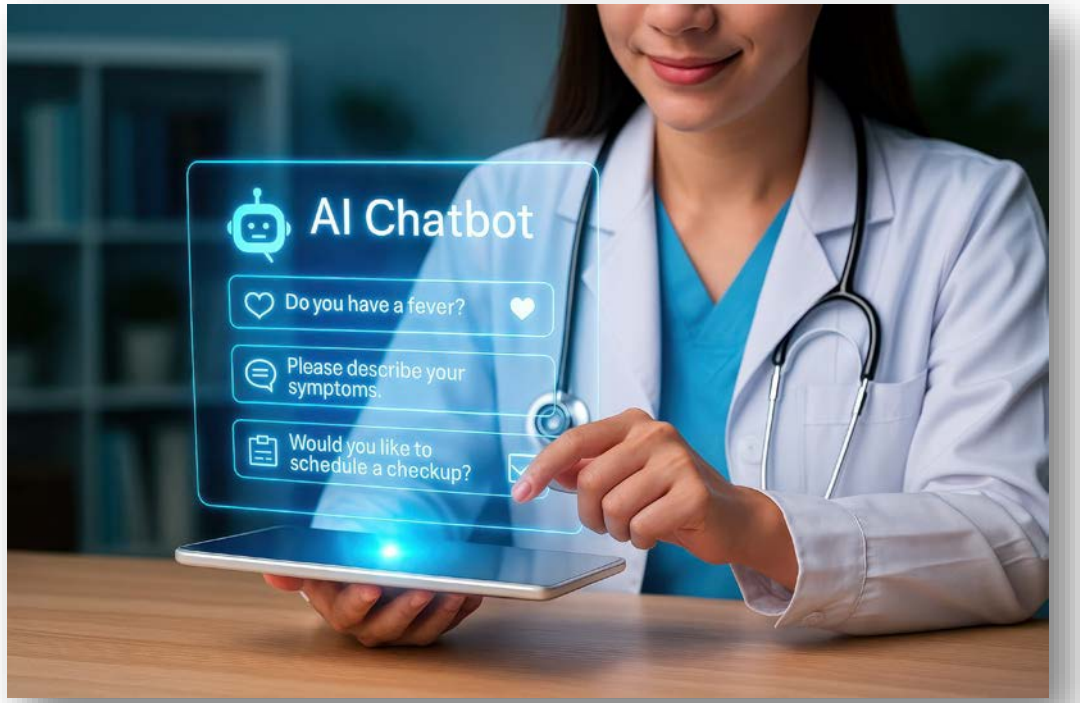
'Unbelievably dangerous': experts sound alarm after ChatGPT Health fails to recognise medical emergencies

Study finds ChatGPT Health did not recommend a hospital visit when medically necessary in more than half of cases

Medical device functionality without evaluation of safety or effectiveness

- "AI chatbots were far more likely than doctors to suggest unnecessary tests and medications. In fact, it recommended **unnecessary tests in more than 90 per cent of cases** and **prescribed inappropriate medications in more than half**" – University of Melbourne, 2025
- "On their own, the LLMs correctly identified conditions in 95% of cases and chose a correct course of action, on average, 56% of the time. However, **when the participants used the LLMs**, relevant conditions were identified in **less than 35%** of the scenarios and a correct course of action was chosen in **less than 44%**." – Andronicos, 2026
- "In **51.6% of cases** where someone needed to go to the **hospital immediately**, the **platform said stay home** or book a routine medical appointment" – Davey, 2026
- **"What worries me most is the false sense of security these systems create. If someone is told to wait 48 hours during an asthma attack or diabetic crisis, that reassurance could cost them their life"**

Key safety concerns



- **Functionality may meet the definition of a medical device**
- **Public usage has increased and rapidly growing**
- **Concerns about clinical suggestions directly to patients and reliability of information**
- **No regulatory visibility or oversight**

Goals of the TGA's chatbot review – currently in scoping stage!

SAFETY

- Protect public health by ensuring AI chatbots with medical device functionality are safe and effective
- A small number of devices could impact a large population due to their accessibility by public users

SCOPING & EDUCATION

- Identify current suppliers in Australia
- Clarify functionality
- Educate stakeholders on regulatory obligation during development and upgrades

COMPLIANCE

Medical device functionality to either be:

- Removed/disabled

  OR

- Included on the ARTG *before* continuing supply

Resources and contacts

Regulation of software based medical devices

https://www.tga.gov.au/regulation-software-based-medical-devices

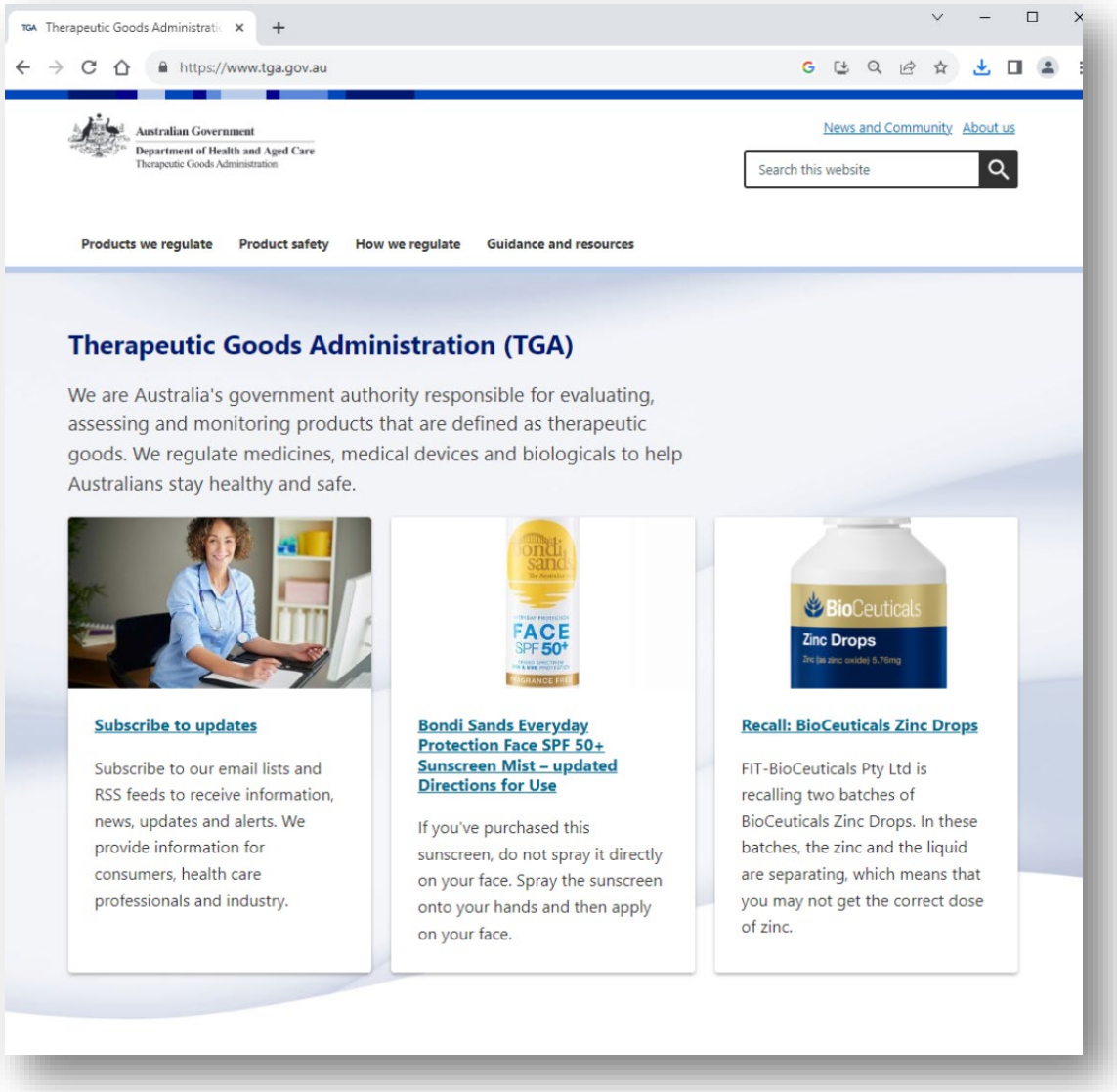
General medical device enquiries

devices@tga.gov.au

1800 141 144

The TGA's Digital Devices team

digital.devices@tga.gov.au



Key learning outcomes

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- Gain awareness of ongoing and upcoming work and how you can provide input/feedback.
- Understand when a digital scribe becomes a medical device.
- Know who to contact and how for more information about software of AI medical devices

Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration