IMDRF International Medical Device Regulators Forum | 26th Session

Regulatory update from TGA Australia

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Electronic IFU for medical devices

- Electronic Instructions For Use (IFU) are currently limited to professional users only where it is not practicable to provide the IFU directly on the device or the device packaging e.g. implantable medical devices.
- Undertook public consultation (Apr-Jun 2024) on the availability of IFUs in more flexible formats
  - Should eIFUs be allowed for a greater range of medical devices, including consumer devices?
  - How long should eIFUs be accessible for?
  - How should eIFUs be stored and accessed?
- Submissions are under review
- Any legislative change will be subject to Government decision.

Clinical Decision Support System (CDSS) software

- CDSS software is exempt when it is intended for the sole purpose of **providing or supporting a recommendation** to a **health professional**
- Issues
  - Incorrect application of the term "clinical decision support" (CDS)
  - Incorrect application of the conditional exemption to in vitro diagnostic medical device (IVD) software
  - Healthcare professionals unable to assess the performance of a CDSS software product
- Undertook public consultation (Mar-May 2024)
  - Introduce a specific definition
  - Clarify diagnostic software (including IVDs) and processing of data
  - Ensure transparency for users on basis of outputs
  - Improve guidance for stakeholders
- Submissions are under review
- Any legislative change will be subject to Government decision.

Vaping reforms – special arrangements for devices

From 1 July 2024

- therapeutic vapes that meet TGA requirements can only be supplied from pharmacies
- advertising or promotion of vapes is prohibited, except where specifically authorised
- importers need to hold an import licence and permit from the Office of Drug Control and meet relevant product standards
- new legislative instruments in place that set out specific device related requirements

From 1 October 2024

- therapeutic vapes containing nicotine or a zero-nicotine substance available for supply in pharmacy settings to patients 18 years or over without a prescription.
- until 30 September 2024, patients need to speak with a medical or nurse practitioner to:
  - get a prescription to buy vapes containing nicotine, and access zero-nicotine vapes

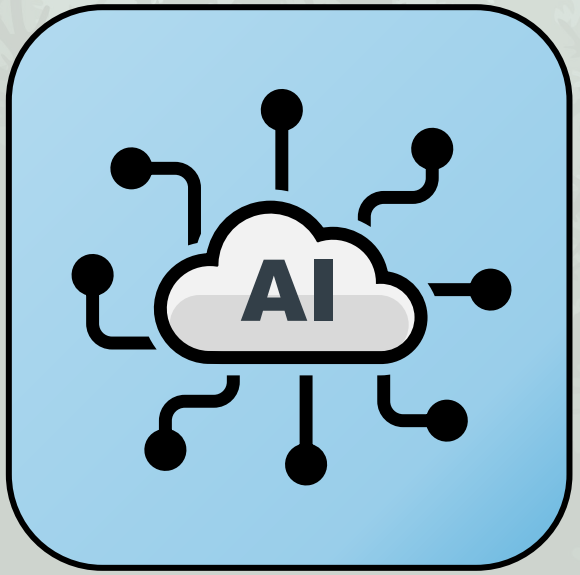
Further upcoming changes:

- reduce permissible nicotine concentrations for all therapeutic vapes

Review of AI and its use in Australia

Clarifying and Strengthening regulations

- The Australian Government has initiated a review of AI across the Australian economy
- Multiple Australian government agencies will address priority areas, including the Department of Health and Aged Care and TGA
- Detailed review of the legislation, regulations and guidance to identify gaps and opportunities relating to AI. This will include reviewing existing exemptions and exclusions
- Targeted stakeholder consultation is currently underway
- Public consultation will follow
- A report will be delivered to government containing the results of our review and options for reform



Proposed guardrails for high-risk AI at a glance

Organisations developing or deploying high-risk AI systems would be required to:

1. Establish, implement and publish an **accountability process** including governance, internal capability and a strategy for regulatory compliance.
2. Establish and implement a **risk management** process to identify and mitigate risks.
3. Protect AI systems and implement data governance measures to manage **data quality** and provenance.
4. **Conduct testing** of an AI model to determine model performance and monitor the system for risks
5. Enable human control or intervention in an AI system to achieve meaningful **human oversight** across the life cycle.
6. Be **transparent with end-users** regarding AI-enabled decisions, interactions with AI and AI-generated content.
7. Establish processes for people impacted by AI systems to **challenge use or outcomes**.
8. Be **transparent with other organisations** throughout the lifecycle of an AI system or model to effectively address risks.
9. Keep and **maintain records** to allow third parties to assess compliance with guardrails.
10. Undertake **conformity assessments** to demonstrate and certify compliance with the guardrails.

The AI Review – options for change

Three key approaches are being considered

Option 1 – adapting existing regulatory frameworks on a sector-specific basis

Under this option we would update our existing framework to address any gaps with the proposed guardrails

Similar approach to the UK's white paper **AI regulation: a pro-innovation approach – proposal policy**

Statement of expectation for regulators

Emerging as a TGA stakeholder preference

Option 2 – adapting existing regulatory frameworks through framework legislation

Government-defined framework legislation

Guardrails would apply to high-risk settings

Responsibility for applying the legislation would still rest with regulators but a compelling policy reason would need to be applied if the provisions are not applied

Option 3 – introducing new AI-specific legislation

New AI legislation mandating the guardrails

A monitoring and enforcement regime overseen by an independent regulator

A similar approach to the EU's AI Act and Canada's Artificial Intelligence and Data Bill

Other Medical Device Reforms

Medical Device Reform	Status
Unique Device Identifier (UDI)	On track for launch in early 2025
Medical Device Vigilance Program	On-site inspections underway, with positive feedback!
Mandatory Adverse Event Reporting	Data operability discussions are continuing with States and Territories, with regulations to be in place by March 2025
Exempt medical devices	Reviewing consultation responses
Boundary and combination products	Further consultations underway to legislate regulatory categories for certain products
Application review audit framework	Finalising dynamic risk factors framework to provide greater transparency and predictability
In-house IVD arrangements	Review to commence late 2024

Recent regulatory changes

- Exemption for prescription spectacle lenses (came into effect on 15 June 2024)
- Expansion of transitional arrangements for software based medical devices (came into effect on 15 June 2024)
- Changes to application audit requirements for medical device inclusion applications (came into effect on 1 July 2024)
- Changes to the classification of devices containing substances of animal, microbial or recombinant origin (came into effect on 1 July 2024)

More information is available at

https://www.tga.gov.au/news/news/medical-device-regulation-changes

Recent, current and upcoming public consultations

Consultation Topic	Consultation Intent	Dates
Electronic Instructions for Use (eIFUs)	Review requirements for electronic Instructions for Use (eIFU) for professional users and consumers.	Closed 28 May 2024
Exempt devices and other therapeutic goods	Review the regulatory requirements for medical devices and other therapeutic goods that are exempt from certain premarket requirements.	Closed 14 June 2024
Boundary and combination products	Improve certainty for products that do not fit clearly in definitions of medical devices or medicines through legislation, including consideration of transition timeframes for affected products.	Closed 20 Aug 2024
Assistive Technologies	Review the regulatory requirements for assistive technologies including the current exclusions and exemptions, particularly for devices used by participants of the National Disability Insurance Scheme and aged care programs.	22 Jul – 13 Oct 2024
Essential Principles	Changes that may be required to the Essential Principles to align with the EU, where appropriate.	7 Aug – 16 Oct 2024
IVD definitions and classifications	Review Australia's alignment with the EU classification system and definitions for IVD medical devices.	Q3 2024
Conformity Assessment Procedures	Review the Australian Conformity Assessment Procedures including where appropriate, alignment with the EU.	Q3 2024
Products without a medical purpose	Refinements for products without a medical intended purpose and the associated transitional timeframe.	Q4 2024
Software-based medical devices	Regulatory changes to allow the TGA to collect and publish more detailed information about medical devices that are standalone software or that incorporate software including artificial intelligence.	Q4 2024

2024 Spirit of Service Awards Finalist!

- The TGA's Medical Devices Consumer Working Group is one of three finalists in the Community category!
- Spirit of Service Awards are administered by the Institute of Public Administration in Australia, and showcase initiatives that are driving positive change for Australia's communities.
- The TGA Medical Device Consumer Working Group
  - comprises 19 consumer organisations and 2 independent representatives
  - is a forum for TGA to seek consumer perspectives on medical device reforms
  - plays an advisory role, lending expertise through members' lived experience or those whom the members represent

More information is available at

https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/medical-devices-consumer-working-group-mdcwg

https://act.ipaa.org.au/2024-spirit-of-service-awards-finalists/

U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

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THANK YOU