Regulatory Developments

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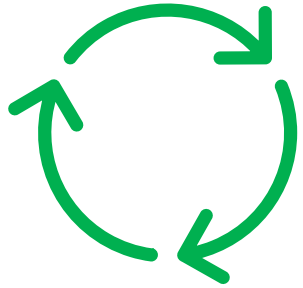
Andrea Osmond-Russell - Image courtesy of ARCS

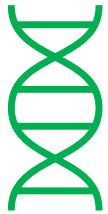
Outline

- The TGA - Priorities and challenges
- Medical Devices and Product Quality
- Regulatory Practice and Support
- Medicines Regulation

TGA Overview

Rapidly evolving regulatory environment





Innovative therapeutics development

Cost recovery

Changing global environment

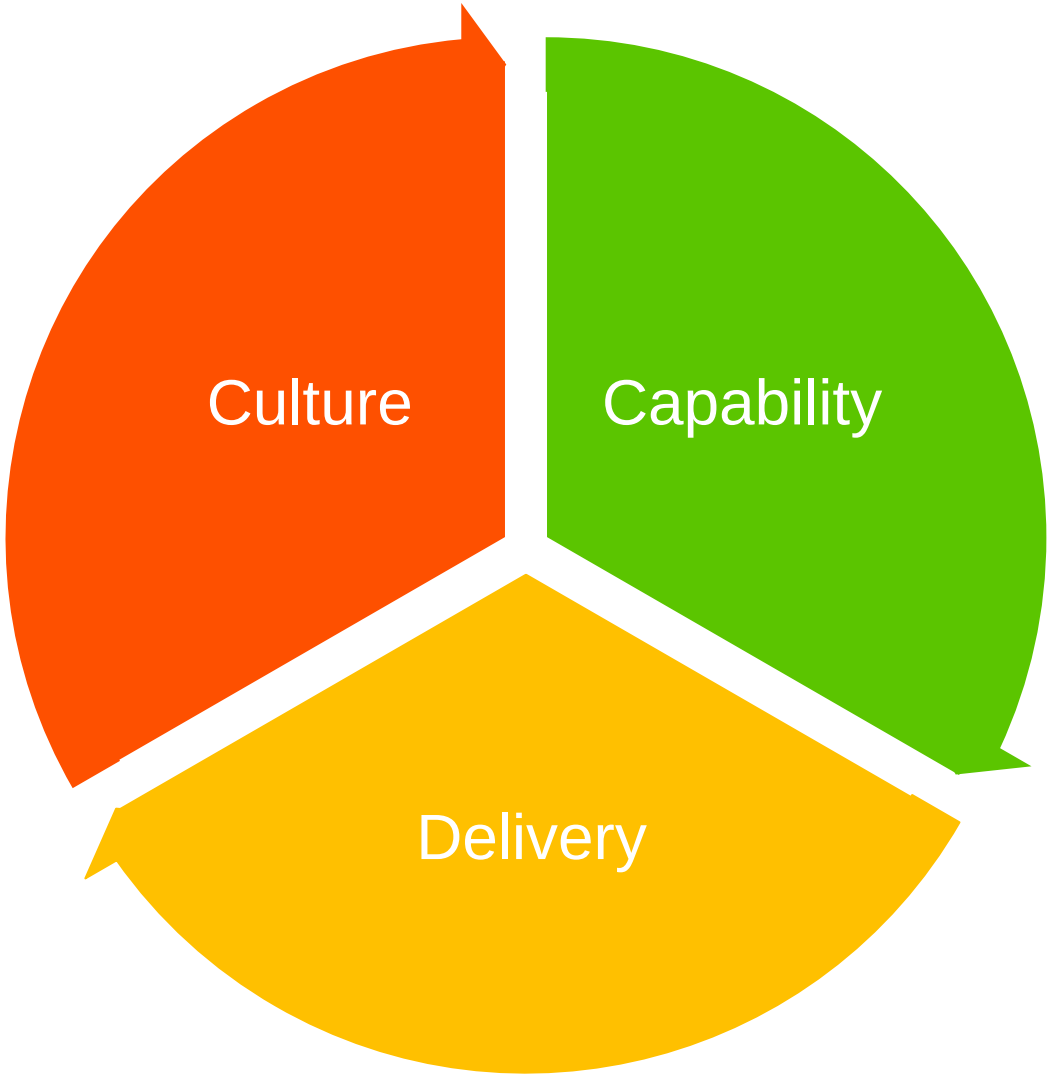
How we respond

Engaging with risk

Resilience in regulation

Use of data and AI

Strategic Intent



Medical Devices & Product Quality

Software as a Medical Device (SaMD) and AI Review

Work is continuing to address the findings from our review in 5 priority areas

Priority Area 1

Supporting stakeholders

Priority Area 2

Robust regulation

Priority Area 3

Reinforce roles & responsibilities

Priority Area 4

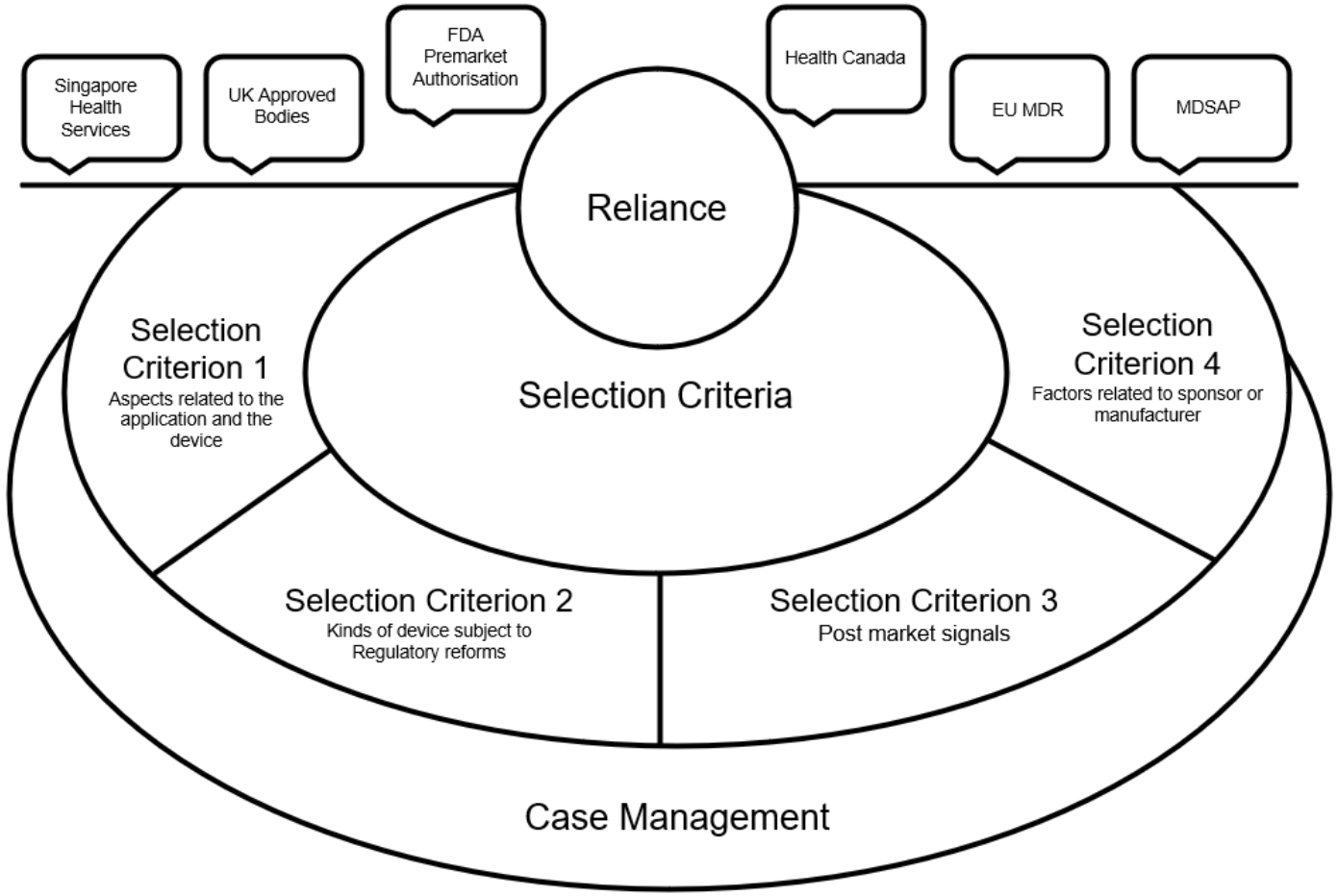
Improve transparency of AI use

Priority Area 5

Conducting compliance

Medical Device application audit framework

- Using evidence from comparable overseas regulators streamlines application reviews
- Enabled pathways improve market access
- Clear guidance and risk criteria support predictable audits
- Risk-based audit model targets higher-risk applications and critical evidence
- Improved case management boosts timeliness and communication
- Ongoing refinement maintains efficiency, safety and performance

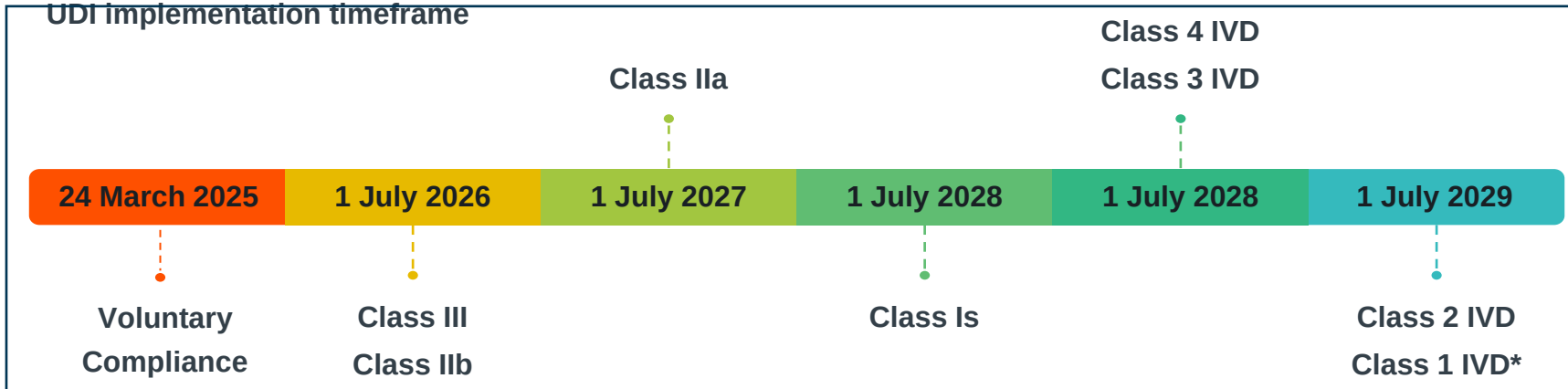


Unique Device Identification (UDI) in Australia

Mandatory compliance begins on 1 July 2026 for Class III and IIb medical devices.

Sponsors unable to meet UDI requirements can utilise streamlined Consent to Supply process.

UDI implementation timeframe



UDI requirements

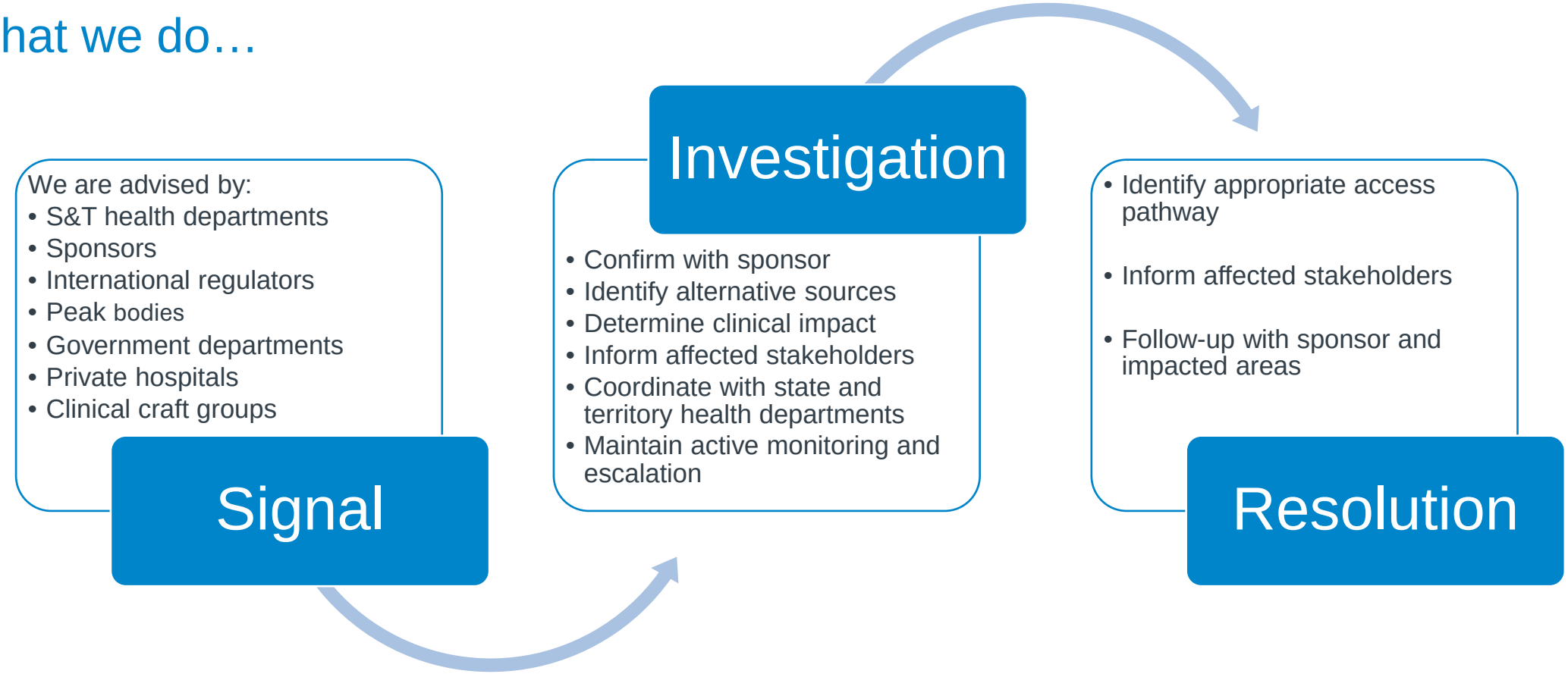
- UDI assigned and shown on labels for each model of device
- UDI records of device data in the Australian UDI Database (AusUDID)
- UDI records linked to the relevant Australian Register of Therapeutic Goods (ARTG) inclusion(s)

UDI Consent to Supply

For more information on the UDI Consent to Supply process, visit the UDI Hub:

Medical device supply disruptions

What we do…



Contact MD.SupplyDisruptions@health.gov.au to provide information on any potential of actual supply disruptions, including raw material shortages, unexpected demand surges, natural disasters or incidents, or device discontinuation

Regulatory Practice and Support

Current compliance principles and focus

The TGA's compliance principles from 1 January 2026 to 31 December 2027:

1. Safeguarding therapeutic goods
2. Educating to empower
3. Protecting those most at risk
4. Leveraging digital capability
5. Strengthening enforcement

Urgent compliance issues will continue to be addressed as they arise, ensuring public health protection remains paramount.

Priority focus areas

- Direct to consumer in vitro diagnostic (IVD) kits
- Erectile dysfunction medications
- Foetal dopplers
- Listed medicines advertising
- Medicinal cannabis
- Melatonin
- Peptides
- Software as a Medical Device (SaMD)
- Substandard and falsified therapeutic goods
- Sunscreens
- Therapeutic goods used in cosmetic procedures
- Vaping goods
- Weight loss medications

TGA Regulatory Compliance

From 1 July 2025 to 31 December 2025:

- **Over 13,000** alleged non-compliance reports
- **Over 4 million** therapeutic goods seized
- **Over 5,000** warning letters issued
- **Over 75** infringement notices issued
- **Over 13,000** unlawful advertisements requested for removal
- Critical **safety alerts** issued for public awareness, including for counterfeit Botox, melatonin, unregistered GLP-1 weight-loss, and methylene blue products.

Compliance for therapeutic vapes

Therapeutic vaping goods must **be notified to the TGA and meet product standards** including minimum requirements for:

Safety + **Quality** + **Performance**

Strengthened product standards apply to all therapeutic vaping goods supplied in Australia from 1 July 2025

Ingredients **Packaging** **Labelling** **Product standards**

Pharmacy sales, goods dispensed and notified vapes

There are over 1,000 notified therapeutic vaping goods on TGA's notified vape list

Between July 2024 and March 2026, more than 420,000 therapeutic vaping goods were sold in pharmacies

Between 1 January 2024 and 31 December 2025, more than 2500 pharmacies supplied therapeutic vaping goods

Enforcement – vapes and emerging nicotine products

- Strong operational relationships with the ABF, AFP and state and territory health and policing agencies.
- Work is underpinned by the **National Vaping Enforcement Framework.**
- We work with strategic partners, such as the Illicit Tobacco and E-Cigarette Commissioner.

Participated in 56 multi-agency activities

Over 19 million unlawful vaping products (removed from the market by ABF/TGA since 1 January 2024

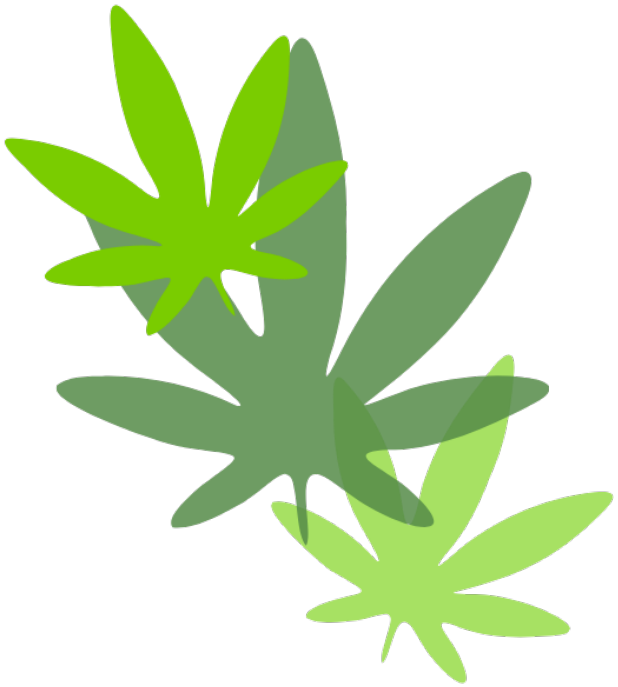
88 infringement notices issued worth almost $1.4 million

Since 1 July 2024

350+ websites disrupted	**600+referrals assessed**
8500+ social media post take downs	**Enforcement actions progressing**

Medicinal Cannabis Regulatory Reforms

Consultation: safety and regulatory oversight of unapproved medicinal cannabis products



786 consultation submissions received

Key findings:

- Lack of awareness regarding the unapproved status of most medicinal cannabis products
- Greater enforcement of quality standards and strengthened labelling requirements
- Safety concerns with certain dosage forms and routes of administration
- THC safety risks and proposed concentration limits
- Safety profile of CBD and other cannabinoids and the need for further research
- Access for at-risk populations

Next steps

Short term:
public awareness
Communication activities to raise awareness

Medium term:
risk mitigation
Consider current scheduling arrangements, reviewing quality requirements

Long term: regulatory reform
Regulatory reform options co-developed with stakeholders and recommendations to be considered by government

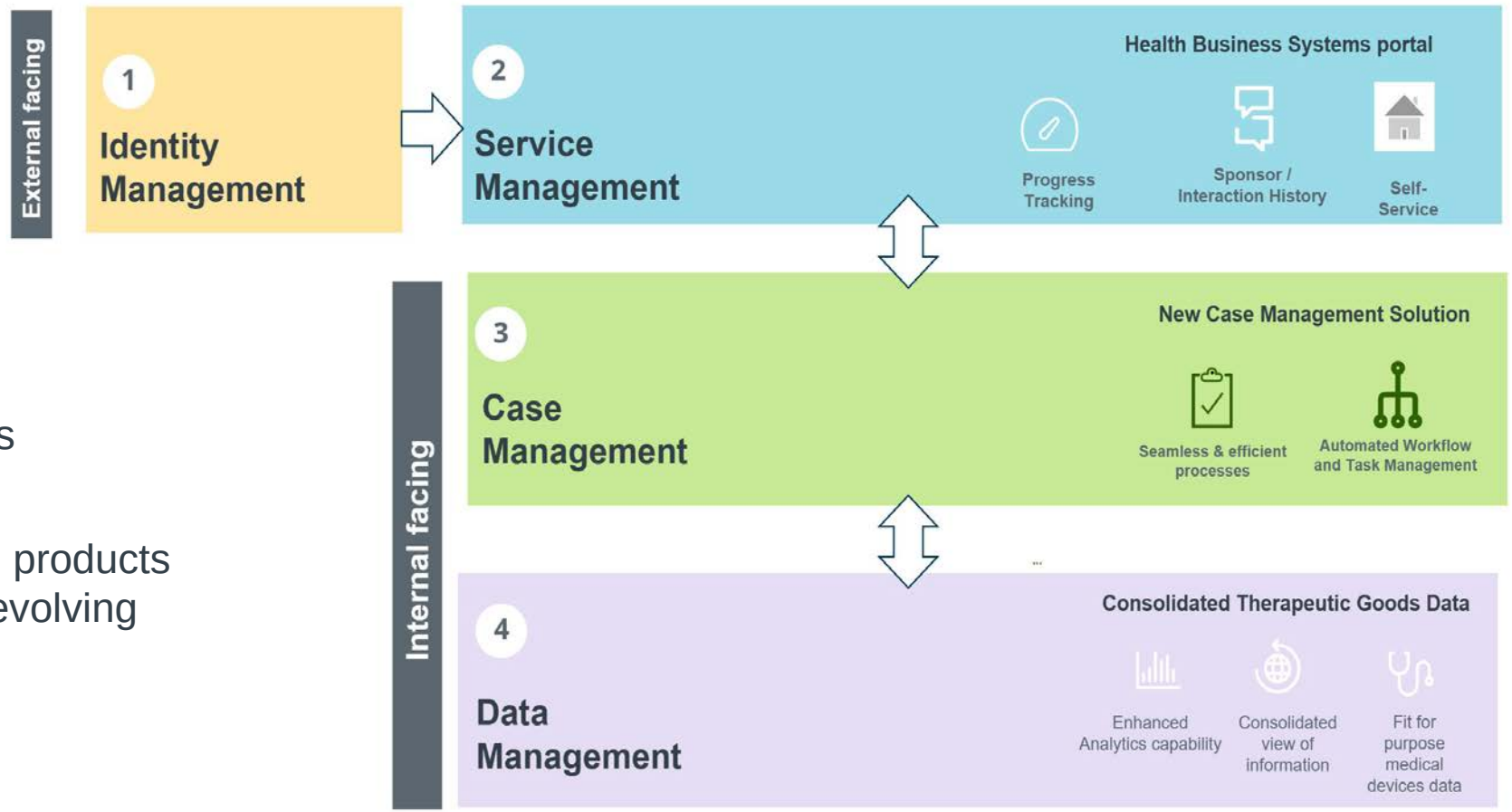
TGA Digital Portfolio Progress Update

Improve the industry customer experience

Improve the staff experience

Improve business intelligence outcomes

Deliver robust digital products that can adapt with evolving requirements



HPRGDigitalBranch@health.gov.au

Medicines Regulation

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

Clinical Stream Redistribution

- PMAB has streamlined clinical evaluation sections from 6 to 5 sections.
- Therapeutic areas have been redistributed to better align workload and expertise.
- Biologicals work has transitioned to the Scientific Evaluation Branch, aligning scientific, policy and decision functions.
- Pharmacist evaluation capacity continues to expanded across submission types.

Artificial Intelligence

Near-term capability

Copilot embedded

Copilot licenses have been delivered to staff

Building staff confidence and capability

Increased **integration** into our business-as-usual

Current state:

Adoption of tools, investigating options to optimise processes for staff and sponsors.

Broader uplift

Dossier management

Improving how complex dossiers are navigated and managed.

Reducing manual handling across routine workflow.

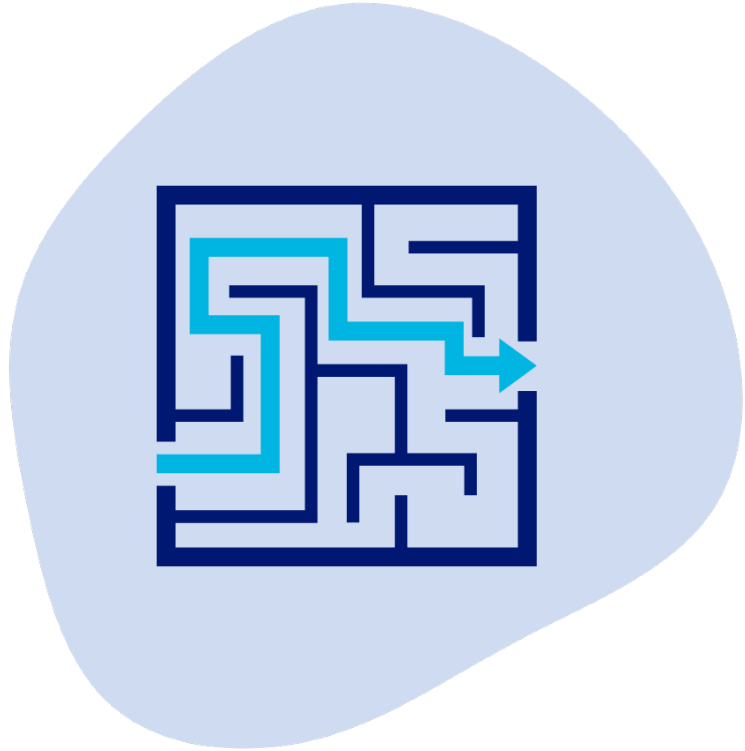
Exploring **fit-for-purpose AI** and **automation** where appropriate.

Future state:

Staff effort directed at complex tasks, with **AI supporting decision makers.**

Risk Appetite and Role of Advisory Committees

- **Balance** medicine access with safety, quality and efficacy
- **Independent advice** supports delegate decisions
- **Advisory committees** used where there is uncertainty, novelty or broader clinical/public health impacts
- **Process**:
  - Delegate poses questions to the Committee
  - Committee provides expert advice
- **Flexible options** means alternative expert advice is available at any time



Sunscreen regulation reform

- Opportunities to improve the current sunscreen regulatory framework.

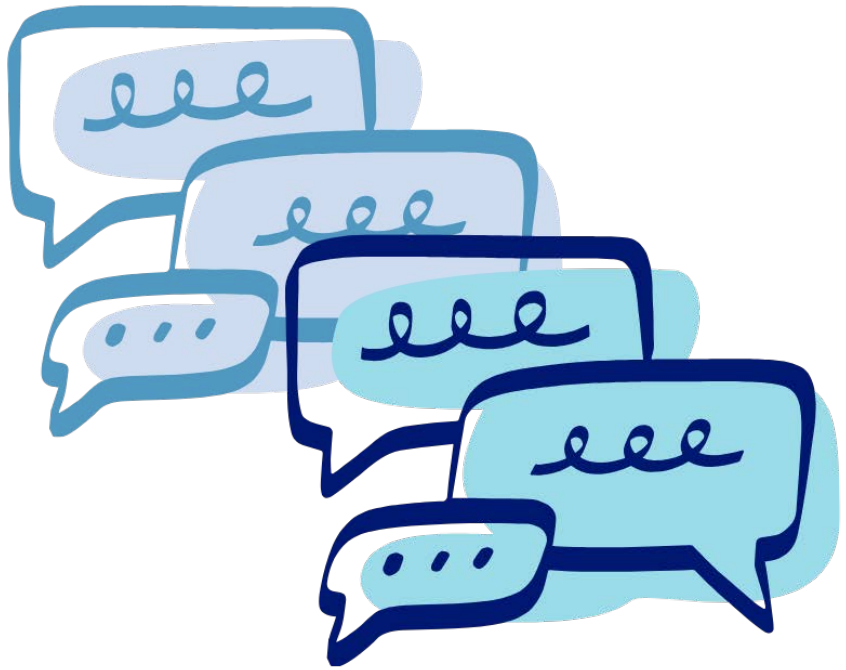
- Key issues include:
    - SPF testing, reliability and labelling
    - oversight of testing laboratories
    - sponsor evidence requirements
    - quality or efficacy concerns
    - excluded cosmetic sunscreens
    - improve manufacturing guidance.

High-moderate risk changes to *Andrographis paniculata*

- Andrographis-induced anaphylactic reactions are unpredictable and difficult to mitigate.
- Updated safety review and supplementary report published on risks of life-threatening anaphylaxis.
- Evidence indicates that:
  - label warnings,
  - formulation controls, or
  - education

  would not adequately mitigate this risk.
- Appears non-commensurate with the low-risk medicines framework.

High-moderate risk changes to *Andrographis paniculata*



What's next?

- Targeted consultation on a proposal to remove Andrographis from the Permissible Ingredients Determination, from April - May 2026
- Currently reviewing all submissions
- Publish consultation outcomes before deciding on next steps
- Updates will be published on the TGA website

International Medicines Collaboration

Access Pilots and International Workshops

Domestic review feeding into cross-agency improvement

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

1

Domestic improvement pilots commenced

Q4 2025

2

Focus areas include governance, peer review, expert advice, expression of interest process review and sponsor communication

Late 2026

3

Virtual cross-agency workshops April–September 2026

Apr–Sep 2026

4

Outputs will inform Access harmonisation

Late 2026

Access reforms are about strengthening Australia's participation in international collaboration so Australians continue to benefit from earlier access to medicines.

Opportunities associated with Chairing ICMRA

Reliance

Facilitating reliance

- Improving access to trusted information
- Improving transparency
- Developing supportive, practical guidelines
- Capacity building
- Maturing regulatory systems

Implementing Reliance

- Common global standards
- Verifying sameness of product
- Mechanisms to share trusted information shared between regulators
- Ensuring processes align

Strengthening Reliance

- Strengthening existing reliance mechanisms
- Support effective adoption of reliance
- Addressing barriers to reliance practices
- Inclusivity
- Increasing trust
- Increasing predictability

Opportunities associated with Chairing ICMRA

Combating mis- and dis-information

The role of regulators as trusted communicators has never been more critical.

Trust

Communication

Information

2025 Edelman Trust Barometer Special Report on Trust and Health reports the erosion of public trust in information from health authorities.

Indo-Pacific Regulatory Strengthening Program (RSP)-2025 Results

Supporting medical product regulation across the Indo-Pacific

Enabled access to

173

essential medicines

Protecting our people: Quality of medicines in Pacific island countries workshop

31

Formal regulatory training sessions delivered

Requests for responsive technical assistance actioned

70

45

Regulatory strengthening activities delivered

Key take-aways

- Strategic reset to a more adaptive, scalable and globally connected regulator
- Risk-based approach focused on greatest public health impact
- Building resilience through strong international collaboration
- Digital and AI driving efficiency, insight and better decision-making
- Reforms strengthening safety, transparency and compliance
- Industry partnerships key to modern regulation and access to safe products

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration