Regulatory Developments

An update from the TGA

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Deputy Secretary
Health Products Regulation Group

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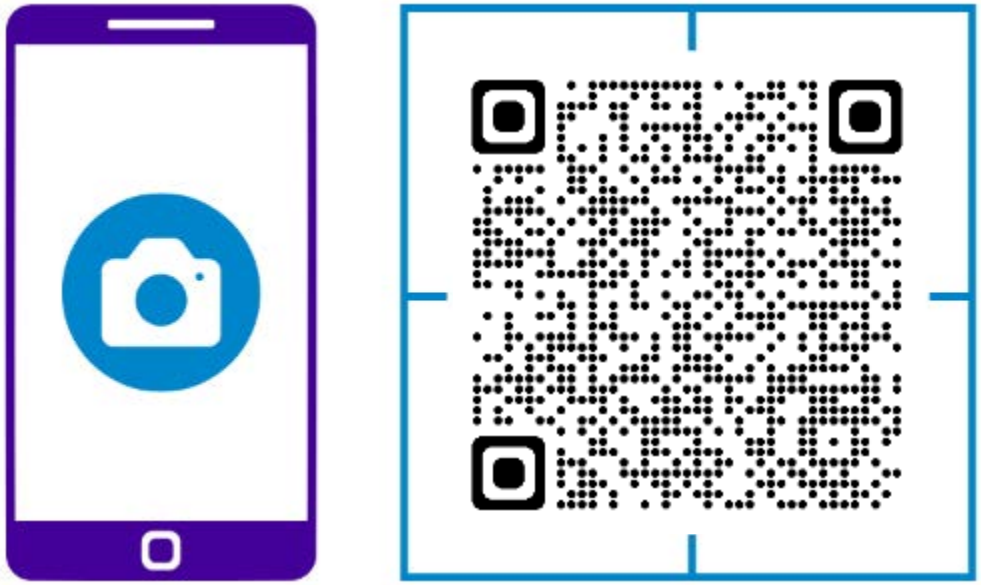
The TGA as a regulator

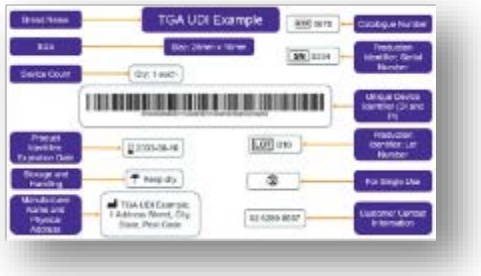
Best practice principles:

- Continuous improvement and building trust
- Risk-based and data-driven
- Stakeholder engagement



Medical Devices

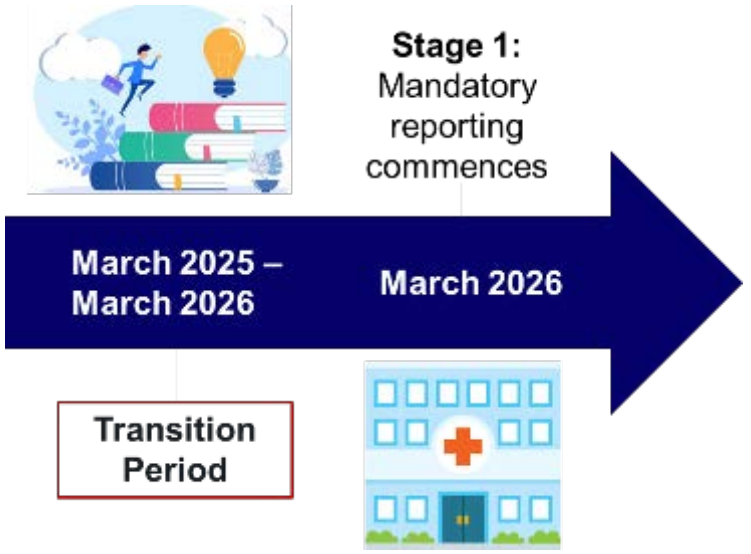
Australian UDI implementation



TGA UDI Hub

udi@health.gov.au

Mandatory Reporting of Adverse Events by Healthcare Facilities



MRSC@health.gov.au

Other medical device reforms

Application Audit Framework
- Transparency & Certainty

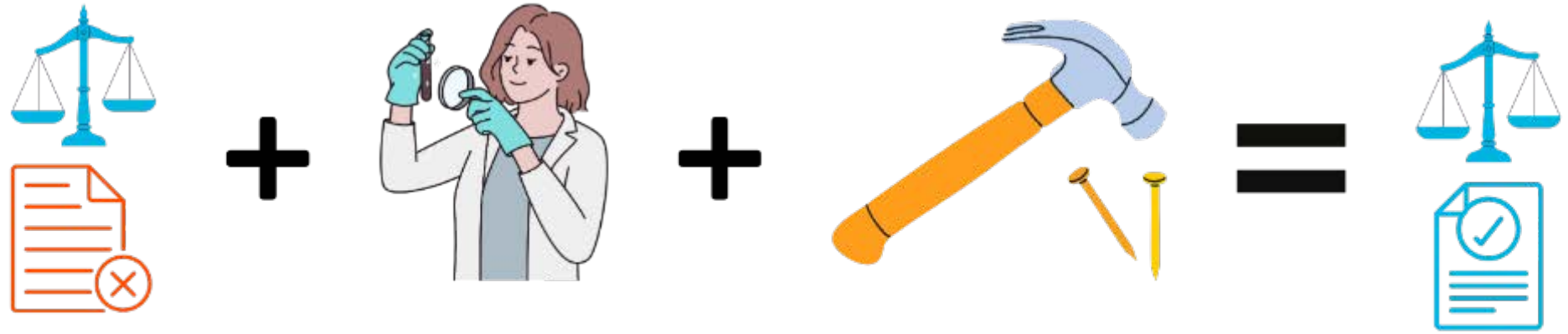
Alignment with Europe

devicereforms@tga.gov.au

TGA Laboratories

Updating the Therapeutic Goods Regulations 1990 for laboratory testing

- Current laboratory testing Regulations are burdensome and limit our ability to test and communicate.
- We are drafting new regulations that align with the outcomes of our public consultation.
- Future work includes updating the laboratory testing information that can be publicly released.



TGA Laboratories

Pacific Medicines Testing Program (PMTP)

TGA & DFAT partner in the Pacific Medicines Testing Program

- providing Pacific Island countries access to Australian laboratory testing
- 13 participating countries
- Laboratory testing of therapeutic goods from participating countries, access to TGA expertise, and some training
- Targets anti biotics, and medicines for non-communicable disease
- 430 samples tested – 25% fail testing

Manufacturing Quality Branch Initiatives

Focus for the next 12 months

- Risk-based strategies to address GMP Clearance backlogs
- Bedding down new recall reforms that commenced in March 2025
- Ongoing support for sovereign manufacturing capability

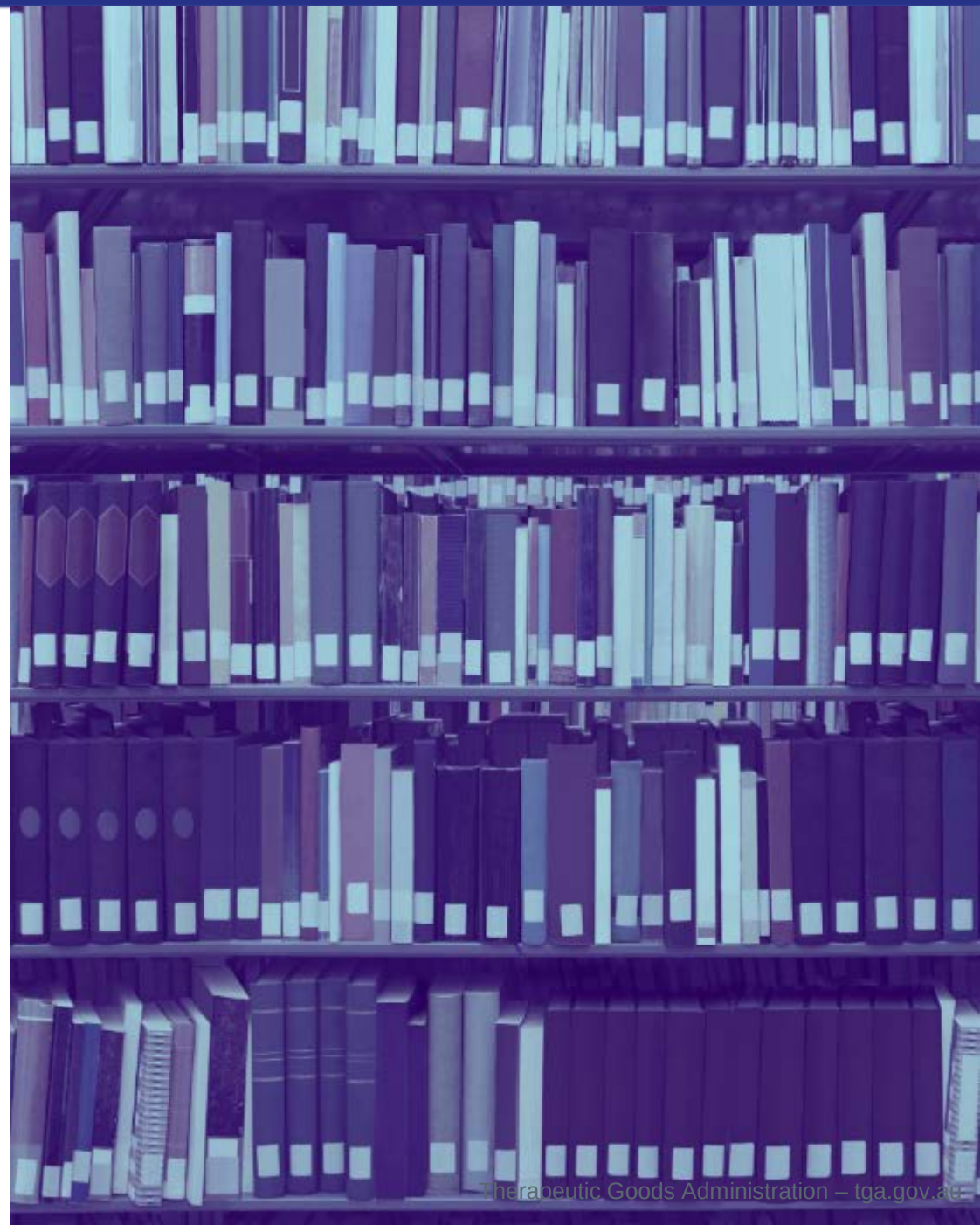
HPRG's Regulatory Legal Services Division

Our legal capability has been bolstered to:

- Enforce the law against those contravene it, for the benefit of the public and of the regulated population who comply with it

- Support HPRG staff to act in accordance with the law

- Facilitate the progression of legislative reforms to the therapeutic goods framework



TGA Regulatory Compliance

An intelligence-led, risk-based approach

- Compliance actions aligned to **Regulatory Compliance Framework** and **compliance priorities**
- Focus on **improving public safety**, **serious breaches** of legislation and **high levels** of non-compliance
- Commencing targeted compliance campaigns in addition to reviewing current compliance priorities

Current compliance priorities:

- Nicotine vaping products
- Medicinal cannabis, psilocybin and MDMA
- Wellness and beauty products
- Substandard and falsified therapeutic goods
- Traditional or alternative treatments

TGA Regulatory Compliance

From 1 July 2024 to 30 April 2025:

- **Over 25,000** alleged non-compliance reports
- **Over 11 million** (non-vape) therapeutic goods seized
- **Over 15,000** warning letters issued
- **Approximately 30** infringement notices to several entities
- **Over 13,000** unlawful advertisements requested for removal
- **Commenced proceedings** against several entities

TGA Regulatory Compliance

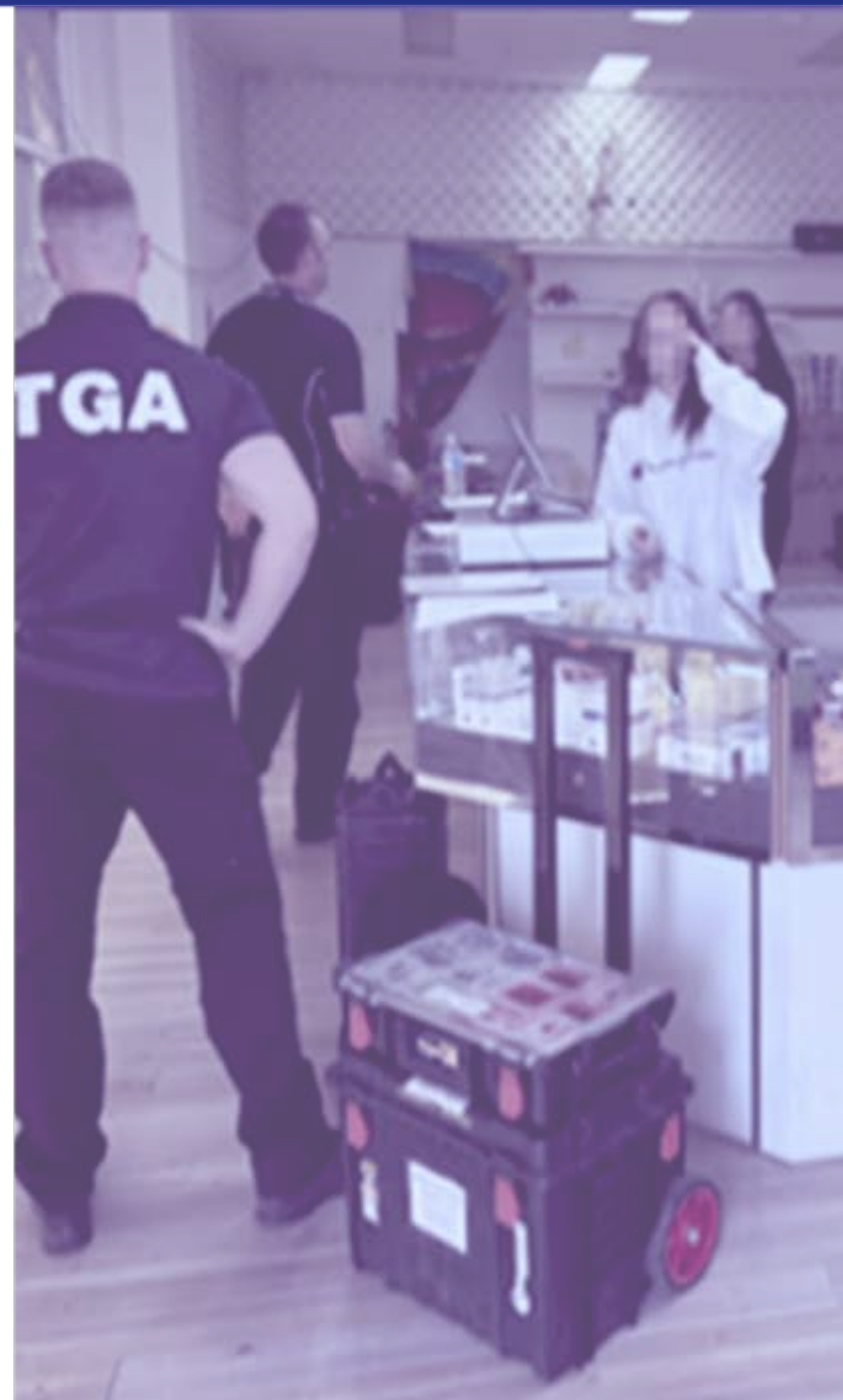
Vaping and novel nicotine products

In partnership with the Australian Border Force (ABF) and state and territory agencies, targeting unlawful importation and supply of vapes and novel nicotine products.

From 1 January 2024 to 2 May 2025:

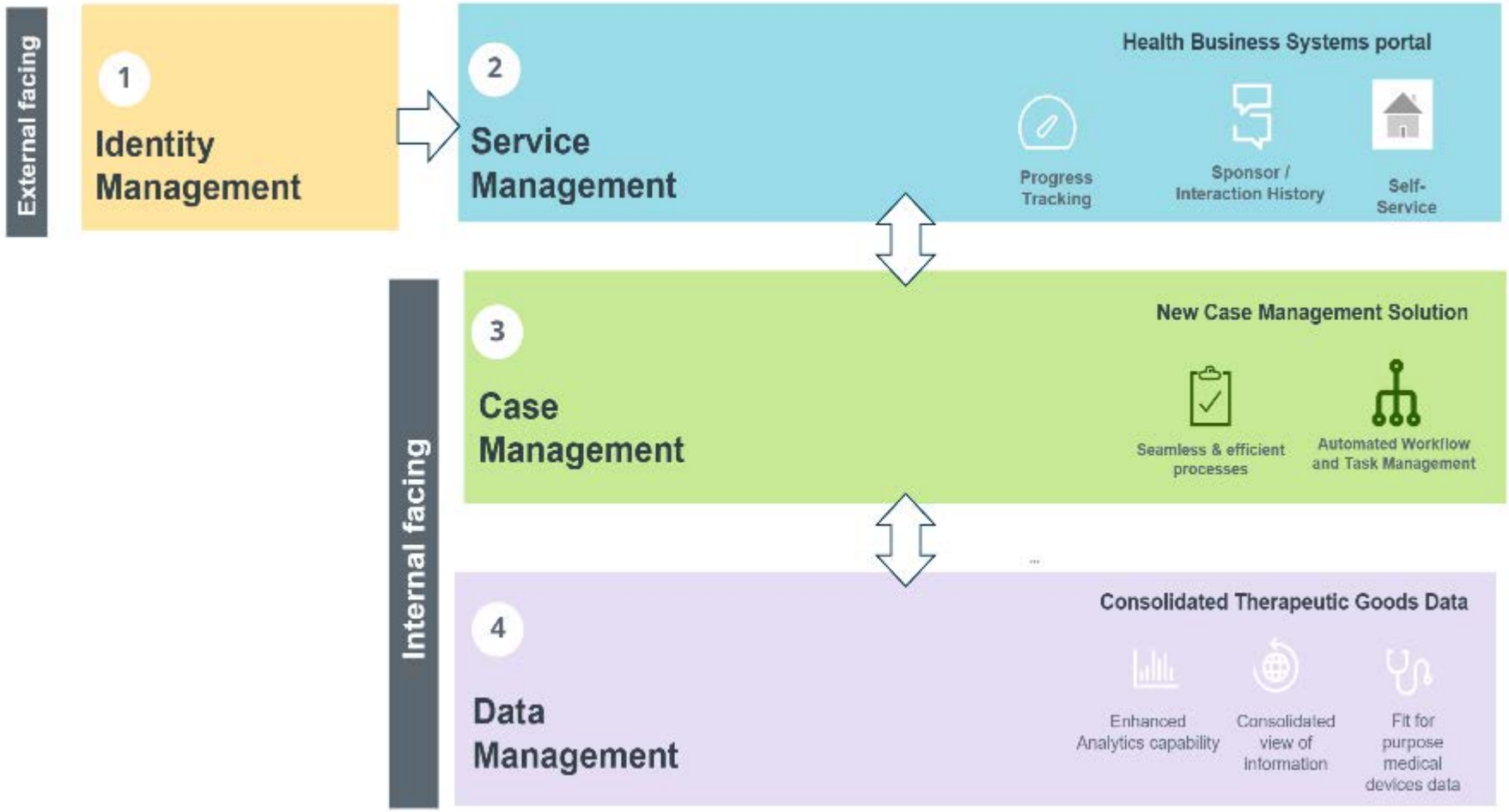
- **more than 8.4 million vaping goods** seized
    - **estimated street value of $422 million**
- **28 joint operations** with state and territory health departments and police agencies, with more planned over 2025
- **78 infringement notices totalling $1,326,552** in relation to unlawful activity regarding vaping goods

TGA has strengthened capacity for compliance and regulation to support early action to address novel nicotine products, in line with the public health risk profile.



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



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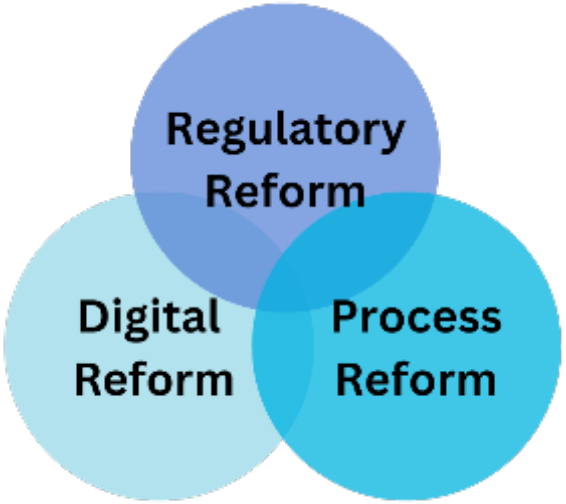
TGA Medicine Shortages and Discontinuations Improvements Roadmap



Update: Medicine Shortages Reforms

Priority Outcome 1
Updated legislative framework to better meet public information needs

Priority Outcome 2
Critical improvements to data and digital infrastructure

Priority Outcome 3
Better access to shortages information for health professionals

Priority Outcome 4
Better sponsor predictions on medicine demand and shortages

1 2 3 4

Priorities announced

November 2024

Sunscreen ingredients review

International

- USFDA and EU reviewed the safety of active sunscreen ingredients

Australia

- Developed Australian Sunscreen Exposure Model (ASEM) with extensive consultation in 2024 and adoption in 2025

- ASEM adopted to facilitate safety reviews of sunscreen ingredients

The Indo-Pacific Regulatory Strengthening Program

Strategic partnership with DFAT under the Australian Government's *Partnerships for a Healthy Region* initiative

Funding: $13.3 million for 2023-2027

Regulatory Strengthening
Strengthen technical knowledge and skills of international counterparts across all regulatory functions

Product Access
Support an increase in registration of, and access to, important medical products

Flexible and Responsive
Regulatory support meets the needs of partner countries and contributes to country, regional and global regulatory systems

Equitable Access
Enabling equitable access to quality-assured, safe and effective medical products to all those who need them

Partnerships
Strong partnerships and collaboration enhance the efficiency and effectiveness of regulatory support

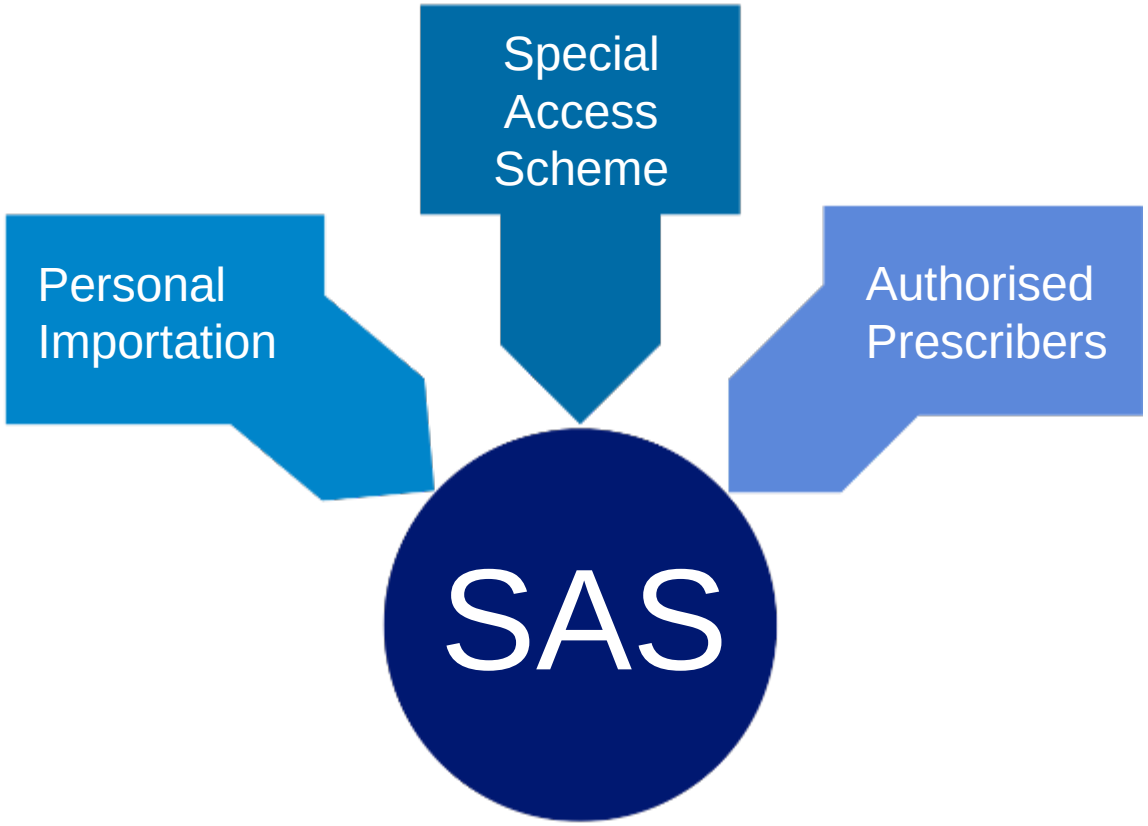
Accessing unapproved therapeutic goods

Patient access pathways

- The TGA encourages the use of therapeutic goods that are included in the ARTG

- Pathways allow access to unapproved products where products included in the ARTG are not clinically appropriate.
  These include the Personal Importation, Special Access and Authorised Prescribers Schemes.

- The TGA cannot guarantee the quality, safety, efficacy and/or performance of ‘unapproved’ therapeutic goods.



Challenge
Implementing process improvements in prescription medicine evaluation

How will AI impact regulatory agencies?

- Advancement in AI adoption is transforming the pharmaceutical industry
- TGA anticipates applications to increase in number, complexity and velocity
- The organisation is looking at opportunities to utilise AI for processes that support our evaluation and decision making of submissions of prescription medicines

Opportunity

Academic Outreach Program and Horizon Scanning

The Academic Outreach Program will enhance awareness and understanding of the TGA's role in regulating therapeutic goods.

It fosters collaboration between complementary sectors and provides valuable resources for students and educators to explore and engage with regulatory science and therapeutic product development.

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration