GMP Forum 2024
Keynote Presentation

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Health Products Regulation Group
and Chief Medical Officer
Department of Health and Aged Care

GMP FORUM 2024

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

GMP FORUM 2024

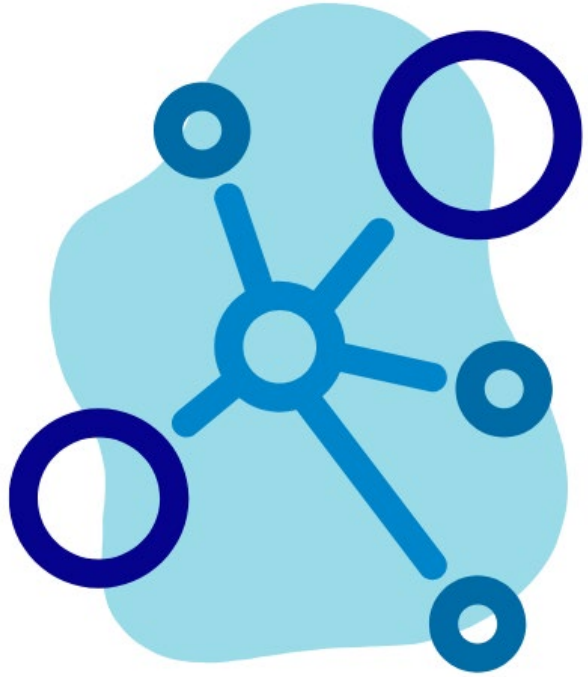
The TGA as Regulator

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

TGA/HPRG Organisational Priorities

Government's Vaping Reforms
Medicinal Cannabis
Compounding

TGA
Reforms



Implement Digital
Transformation

TGA Priorities - Vaping

"These changes will protect Australians, particularly young people, from the harms of vaping and nicotine dependence, while ensuring those with a legitimate need to access therapeutic vapes can continue to do so, where clinically appropriate."

The Hon Mark Butler MP, Minister for Health and Aged Care

Timeline of vaping reforms

Date	Milestone
1 October 2021	Regulatory changes requiring a prescription to access nicotine-containing vapes
2 May 2023	Minister announces action on vaping
28 November 2023	Minister announces enhanced controls on importation, manufacture, advertising, supply and commercial possession of vapes to be implemented throughout 2024
1 January 2024	Import ban for disposable and single-use vapes
1 March 2024	Import of vapes requires a license and permit, product standards enhanced
21 March 2024	Introduction of the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 into Parliament
26 June 2024	Amended Bill passes Senate- schedule 3 (pharmacist-only)
1 October 2024	Therapeutic vapes (containing 20 mg/mL of nicotine or lower) available from participating pharmacies to adults aged 18 years or over, without a prescription

TGA Priorities - Compounding

Case study- compounding of replica weight loss products

- Regulatory “sidestep” and increasing reports of patient harm
- New regulations to remove GLP-1 RAs from the pharmacy compounding exemption
- Compounded products are not identical to the TGA-approved products
- At least 20,000 Australian patients are injecting these compounded products - the majority for weight loss

TGA Priorities - Medicinal Cannabis

- The ‘Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017’ sets out minimum quality requirements for cannabis ingredients and finished products

- In mid-2023 new requirements for GMP and product quality came into effect

  - Evidence that manufacturing of each batch has been done under approved GMP must be available.

  - Acceptable evidence is specified in TGO 93: documents from countries with equivalent regulatory regimes

  - Importers can request the TGA inspect manufacturing sites in any other countries, or where sites do not have the specified GMP evidence.

MC quality requirements - compliance

- The TGA has a structured compliance program
- There is also active encouragement to report poor-quality products and adverse events
- Obligations- and potential offences- involve all parties in the medicinal cannabis supply chain, including manufacturers, sponsors, healthcare practitioners and compounding pharmacists

TGA Priorities – TGA Recalls Reforms

Introducing new terminology

SARA – System for Australian Recall Actions

DRAC – Database of Recalls, Alerts and Corrections

URPTG - Uniform Recall Procedure for Therapeutic Goods

PRAC - Procedure for Recalls, Alerts and Corrections

TGA Priorities – TGA Reforms

Other TGA reforms include

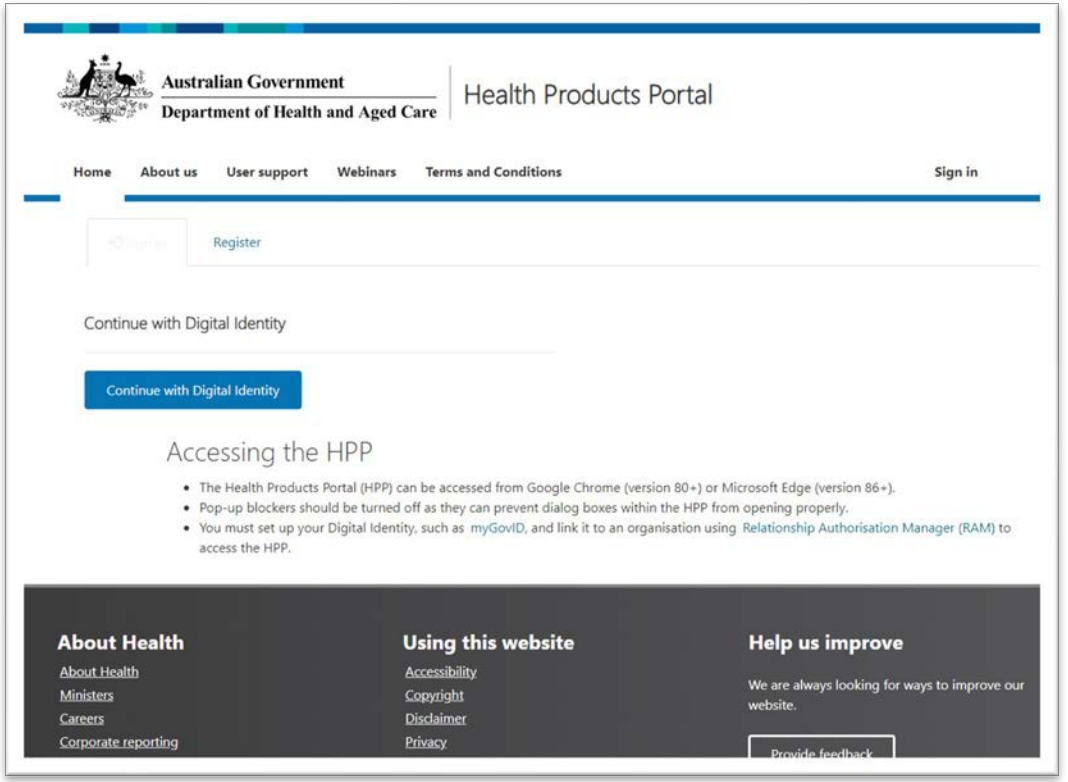
- Medicine shortages management
- Laboratory testing
- Medical devices regulation

TGA Priorities – Implementing Digital Transformation

New Health Business Services portal

- **July 2024** – first instalment of new Health Business Services portal
  - Office of Drug Control – use new online portal to create and manage an account, submit licence applications

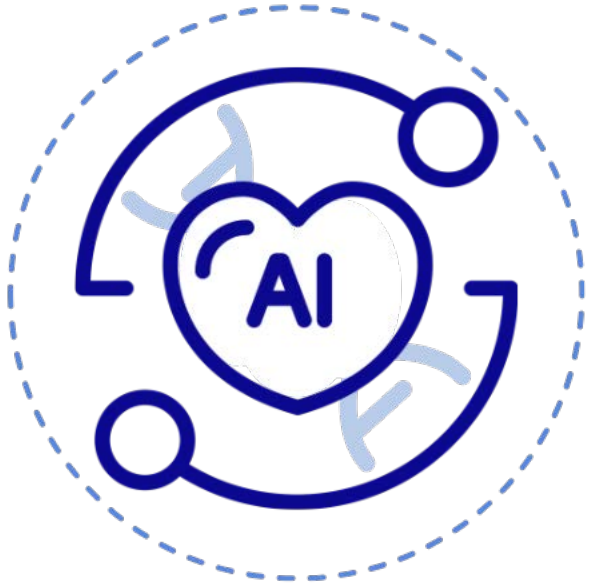
- **Planned from July 2025** –
  - New business portal to include management of invoices
  - Streamlined process for submitting requests for a new ingredient name or pre-submission meeting
  - GMP clearance application



TGA/HPRG Organisational Challenges

Rapidly evolving Scientific World

Continuous evolution of medicines and biologicals



Advances in AI-driven diagnostics

TGA Challenges – Continuous evolution of medicines and biologicals

- Personalised and personal medicines
- 3D printing
- Gene therapies
- Point of care manufacturing
- Combination and boundary products
- Bacteriophages

TGA Challenges – Artificial Intelligence Clarifying and Strengthening Regulation

TGA – priority review of legislation

- How prepared are we for the rising use of AI?
  - Mitigating risks
  - Leveraging opportunities
- How well does our legislation meet the intent of the mandatory guardrails proposed by DISR?

- ***The existing regulatory framework broadly aligns with the proposed guardrails***
- ***Some amendments to the existing regulatory framework and additional guidance/information may be required to ensure all risks are mitigated and opportunities leveraged***
- ***Work is underway around the world to address the increasing use of AI appropriately – TGA remains engaged with work undertaken in other jurisdictions***

Targeted stakeholder consultation

Complete

Public consultation

Closed 20 Oct

Report to government

End of the year

Strengthening relationships with…

Consumers &
Health Professionals

Manufacturers &
Sponsors

International
Regulators

Universities,
Researchers &
Academics

Looking to the future…

Questions?

Scan this QR code with your device to submit a question

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration