Prescription Medicines Authorisation Branch Update

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Session overview

Setting the scene for the panel discussion

1. What PMAB does and what has changed
2. Operational focus: structure, biologicals and workload balance
3. Data and submission trends and what they are telling us
4. Reforms, Access, radiopharmaceuticals, AI and automation

PMAB’s role in prescription medicines regulation

A perspective for industry

Administers and evaluates prescription medicine applications

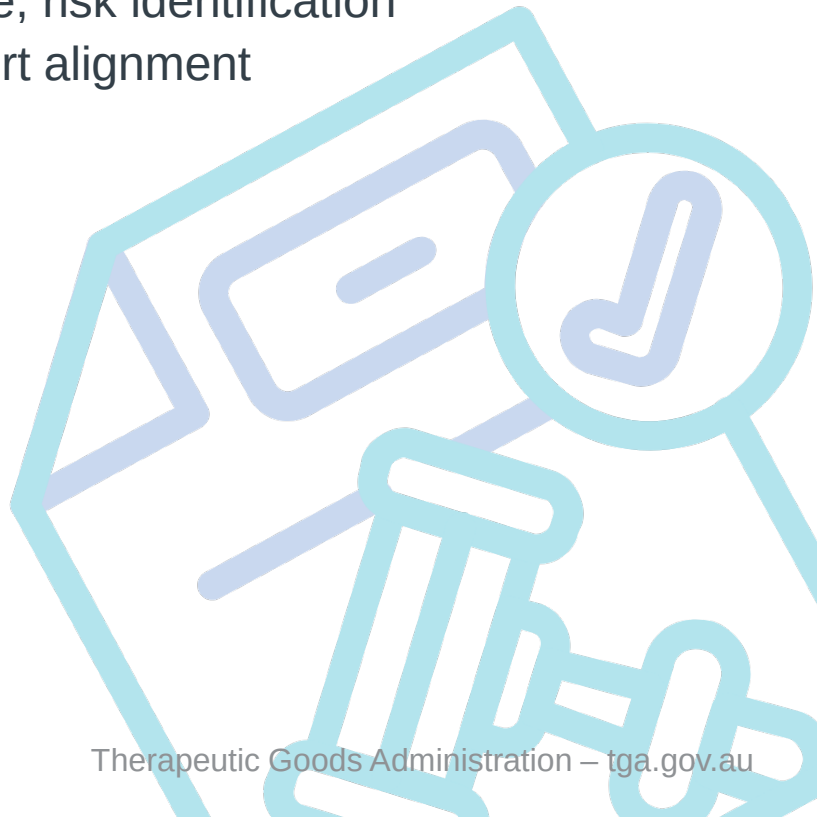
Supports robust, timely and procedurally sound regulatory decisions

Uses data and feedback from industry to understand pressure points and improve operations

Works with domestic and international partners to improve Access pathways

Core business

PMAB is strengthening the prescription medicines regulatory process by improving structure, risk identification and effort alignment



Clinical stream redistribution

A more balanced realignment for sustained demand

What we've done

PMAB has streamlined clinical evaluation sections from 6 to 5

Therapeutic area responsibilities adjusted across teams to better align workload across teams

Support more equitable workload distribution

More flexibility to manage future demand

What this means operationally

A clearer operating model, with more sustainable resourcing and greater ability to direct expertise where demand is highest.

Biologicals work: Clearer branch alignment

Subject matter based assignment of responsibilities between PMAB and SEB

- Responsibility for biological products has transitioned to the Scientific Evaluation Branch

- Evaluation, decision-making and policy responsibility are consolidated to align expertise and improve accountability

- PMAB has adjusted its clinical structure in response

- The objective is clear accountability and more sustainable workloads

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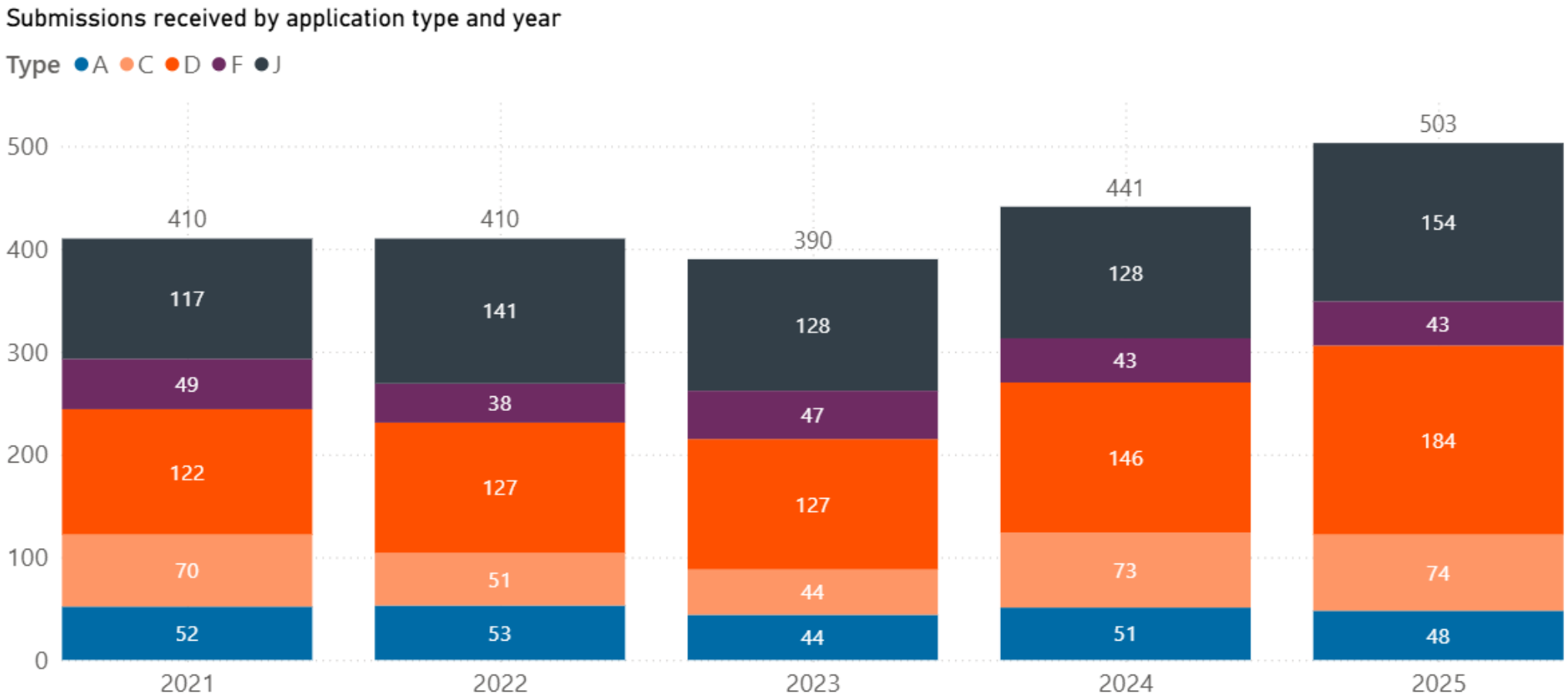
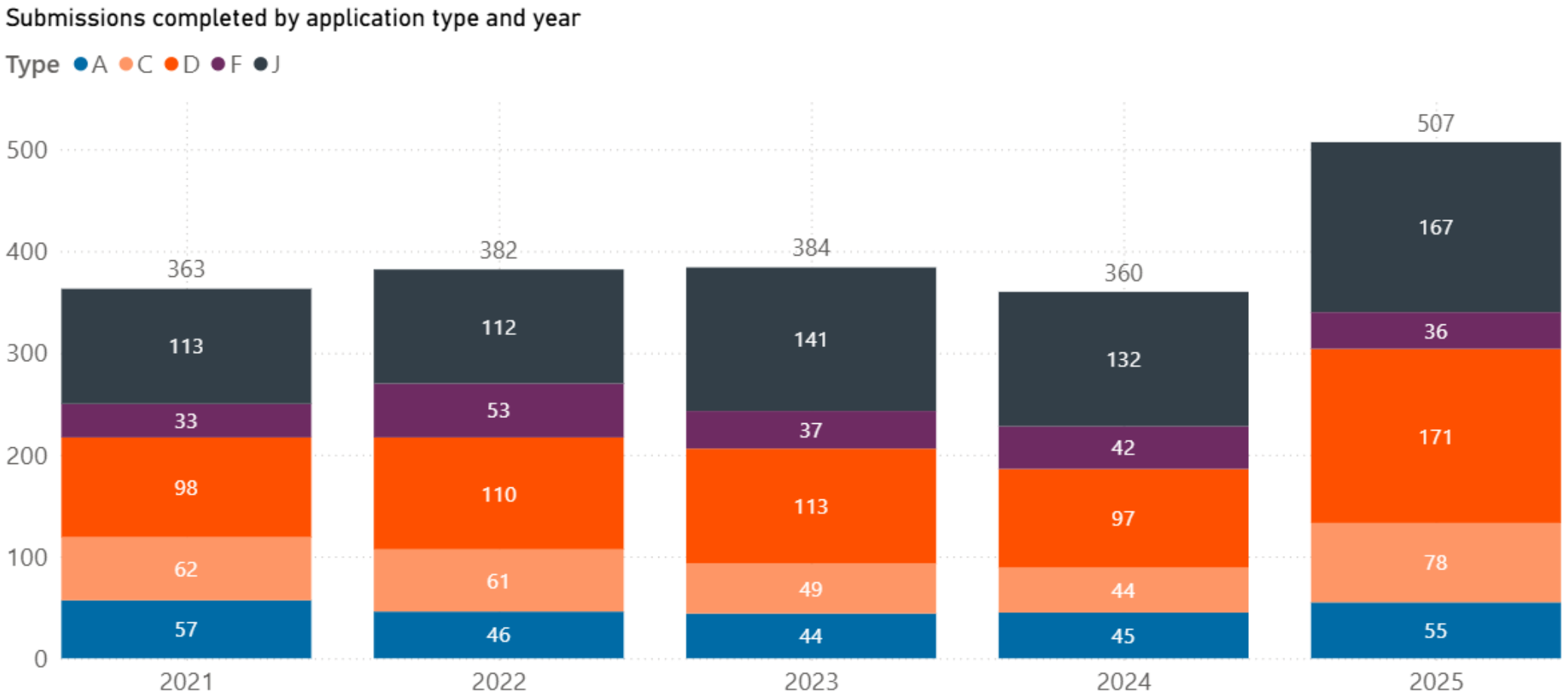
Placing biologicals work where the relevant scientific, policy and decision functions are most closely aligned.

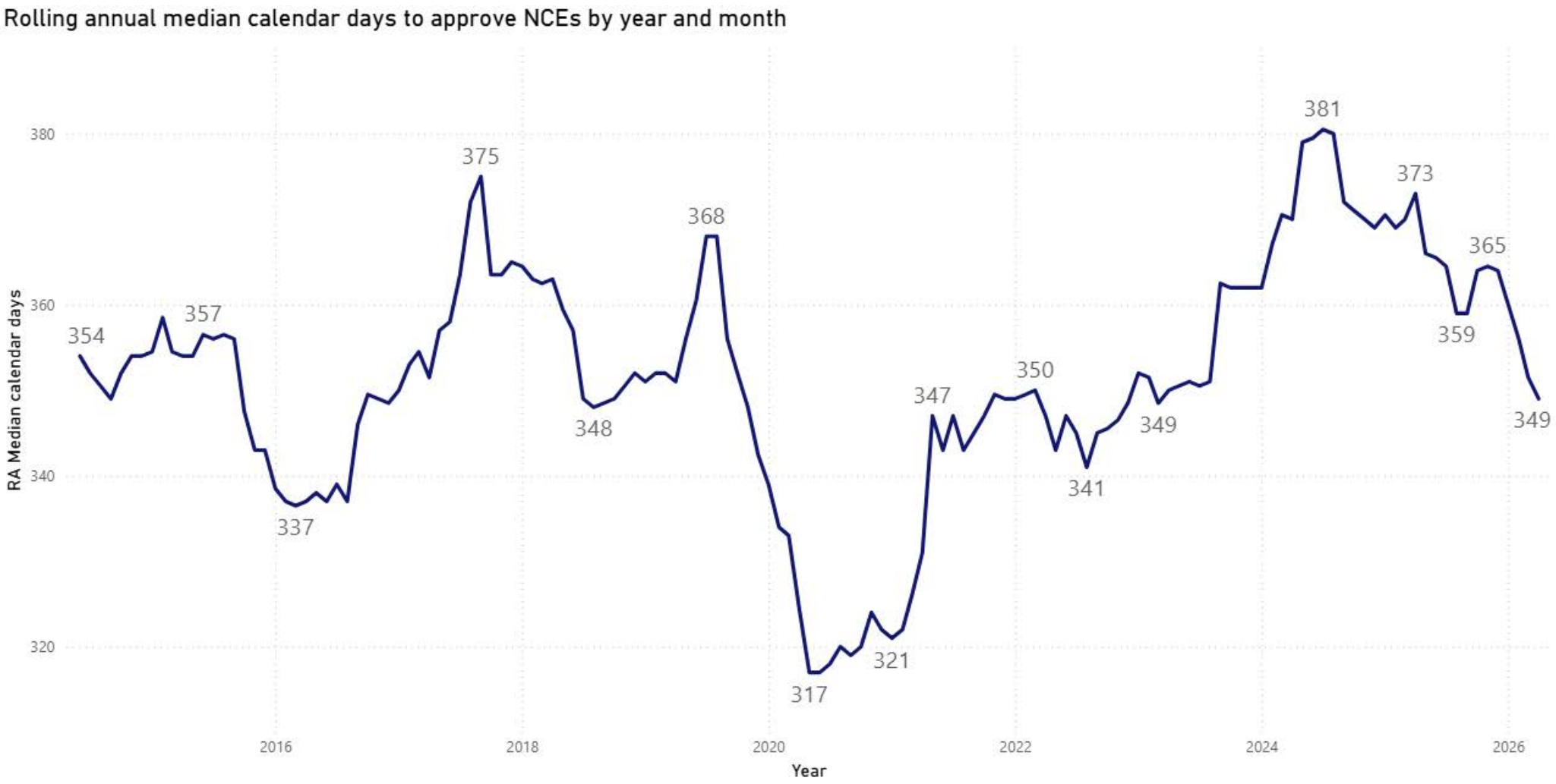
The TGA received a record number of prescription medicine submissions in 2025.



The TGA has been able to avoid a substantial backlog by completing a record number of submissions.



Calendar days to approve NCEs has improved since it peaked in July 2024.



Reforms program spotlight

Improving the registration process through targeted operational reform

Assess efficiency	External quality	Improve performance	Raise standards
Assessing process and workflow efficiency across medicine regulatory activities	Clear expectations for high-quality applications, Including ensuring that mandatory requirements are clear and up to date	Evaluate stop-clock use and the impact of bundled submissions to support transparency, performance and timelines	Reform that improves performance without compromising robust regulatory decisions

OUR AIM: Improve workflows and efficiency while maintaining the delivery of robust, high-quality decisions

AI and automation

Process insights

- ✓ Reviewed end-to-end prescription medicines process and mapped key touchpoints, touch time and cycle time
- ✓ Identified duplication, rework and low-value administrative effort across workflows
- ✓ Mid-term plans to adopt AI tooling and automation to further support staff

AI adoption to support robust and independent human decision making

Where to next?

- ✓ Investigating options to optimise evaluation processes for staff and sponsors
- ✓ Preparing for increased application volume driven by industry innovation
- ✓ Expected delivery timeframe: Q3-Q4 2027

Access work-sharing reform

Strengthening collaboration while retaining independent decision making

Collaborate	Share & learn	Improve	Harmonise
Access supports collaboration and work-sharing	Systematic review of Access operations after internal and sponsor feedback	Focus on communication, process and governance	Cross-agency workshops are underway to inform harmonisation

Why

Access is valuable for Australian patients because it can significantly improve the submission gap between the FDA and Australian. It also needs to work for the TGA and sponsors

Access pilots and international workshops

Domestic learning feeding into cross-agency improvement

1 2 3 4




Domestic improvement pilots commenced	Focus areas include governance, peer review, expert advice, expression of interest process review and sponsor communication	Virtual cross-agency workshops April–September 2026	Learnings will inform an Access harmonisation
Q4 2025	**Late 2026**	**Apr–Sep 2026**	**Late 2026**

PMAB is testing practical ways to make Access more predictable and easier to use.

PANEL PROMPT: What would make Access more predictable from a sponsor perspective?

Radiopharmaceuticals external consultation

Seeking clarity across a complex and evolving regulatory interface

Complex regulation

Involves complex manufacturing, clinical and supply settings

Stakeholder input

Seeking clarity, consistency and more certainty for industry

Consultation

Engagement seeks broader feedback before more targeted consultation

Transparent framing

Understanding our interface and improving outcomes without signaling immediate regulatory change

Consultation open from 5 June 2026 for 8 weeks.

What industry can expect from pmab in 2026

Practical improvements, clearer signals and ongoing engagement

Sustainable and flexible clinical evaluation structures

Alignment of responsibility and subject matter expertise

Data-based focus on submission trends and operational pressure points

Reform work focused on predictability, performance and timeliness

Strategic focus on Access and other international work-sharing opportunities

Consultation and engagement where settings are complex and/or evolving landscape

Invitation

We welcome feedback on what is working, pressure points, and which improvements would make the biggest practical difference.

Panel discussion

Andrew Simpson, Assistant Secretary

Dr Mohit Khera, Principal Medical Officer

Fiona Turk, Director

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration