Reforms on the horizon: Prescription medicines registration

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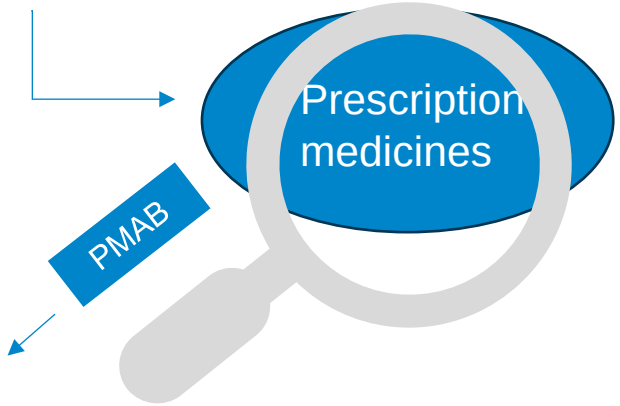
Overview

- Pre-marketing process for prescription medicines registration
- Regulatory phases and milestones
- Emerging trends and impact on our work
- Prescription medicines registration reforms
- Where to next?

Process overview

The TGA safeguards the health of the Australian community through effective and timely regulation of therapeutic goods.

Responsible for evaluating, assessing and monitoring therapeutic products



Evaluates pre-market applications for*:
- new prescription medicines,
- new uses and other variations to prescription medicines registered on the ARTG

Ensuring:
- quality, safety and efficacy
- availability in a timely manner

*Pre-market clinical aspects with advice from other areas in the TGA

Pre-marketing process for prescription medicine applications

Applications supported by nonclinical, clinical/or bioequivalence data (category 1 and category 2)

👉 Key elements

- Pathways
- **Pre-submission planning**
- Applications submission
- **Regulatory requirements**
- Quality of applications
- **Management by milestones**

Emerging trends

In 2024, submission volumes increased by over 20%, exceeding forecasts and creating system challenges

Increasing volumes of submissions and backlog expected to continue due to higher probabilities of success for new medicines, driven by advancements in automation, AI and R&D

Adapting to the evolving landscape

- Strategic focus on optimising processes and resource allocation
- Review and reforms of current practices and tools to enhance efficiency and effectiveness
- Emphasis on innovation and flexibility to meet future demands

TGA's approval times increased by 4.3% in 2023, from a median of 347 calendar days to 362

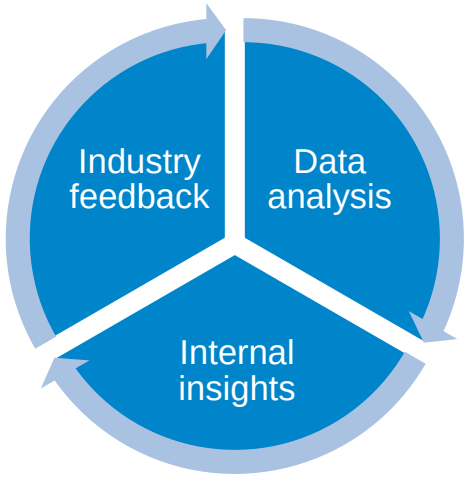
Source: Centre for Innovation in Regulatory Science (CIRS)

Reforms on the horizon

Embarking on medicines registration reforms for sustainable decision predictability and operational excellence

Collaborative approach

Shared expectations

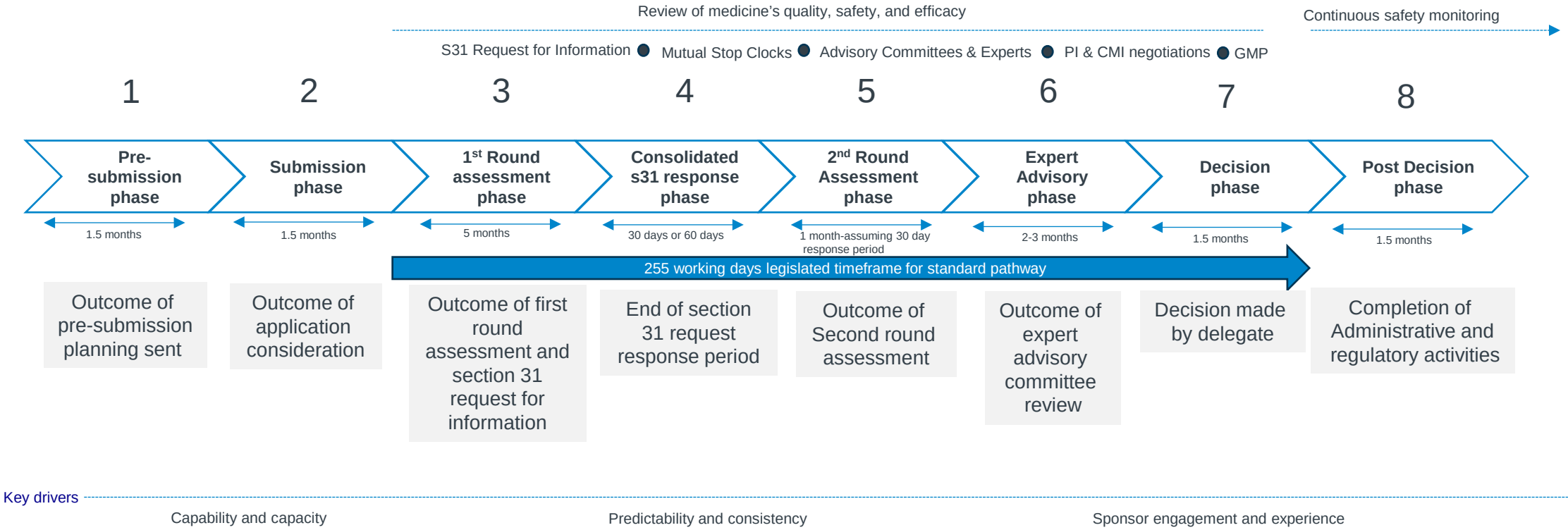


Goals

- Improve access to medicines by **reducing the number of days** to registration
- **Data informed operations** – prioritisation, allocation, risk-identification, and monitoring
- Ensure **consistent registration process** – improve efficiency, consistency and predictability of the registration process
- Enhance **stakeholder experience and engagement** with the registration process
- **Optimise resources and capabilities**, maintain sustainable workloads, retain staff and ensure **sufficient capacity** to undertake work-sharing and other collaborative evaluations
- Leverage **scientific and technological advancements** to maintain rigorous safety and efficacy assessments

Regulatory phases and major activities

Prescription Medicines Registration Process

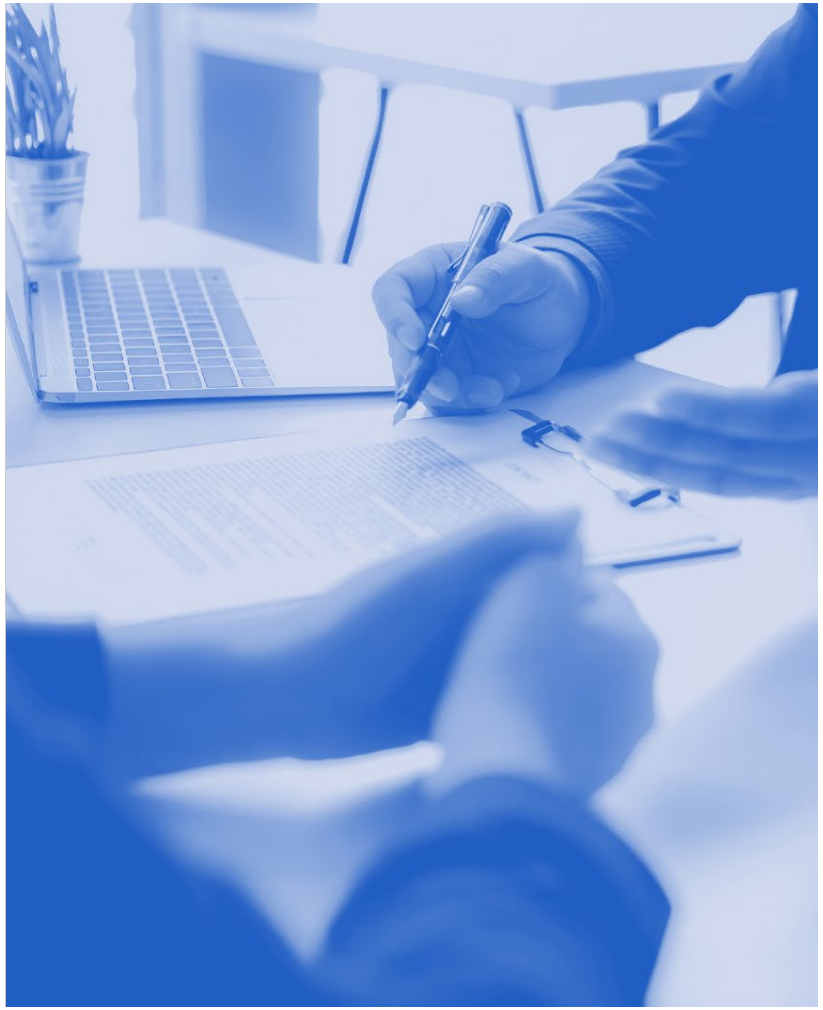


Indicative timeframes

Reforms program

System focused, inclusive and innovative approach

- Operational structure
- Processes, practices, tools and standards
- Communication and engagement practices
- Guidance
- International collaboration initiatives
- Enabling legislation, policy and fees



Approach

Diagnosis and ideation per initial focus area

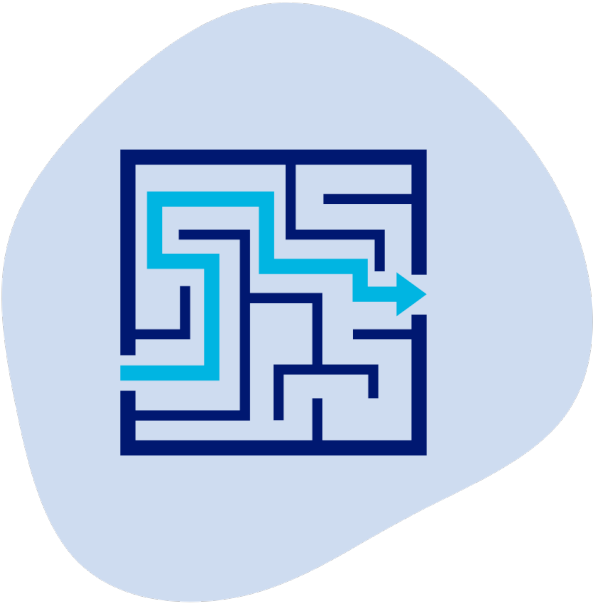
Identify opportunities and potential solutions with stakeholder input

Test and refine including seek feedback from industry and end-users

Monitor and evaluate outcomes

Stakeholder engagement

Going forward



Initial diagnosis and potential solutions identification

Collect insights, refine potential pathways forward

Form stakeholder working groups, initially internal before expanding externally

Regular consultations and targeted workshops as reform work progresses

Ongoing communication and transparency

Regular updates via industry meetings, upcoming annual ARCS in June and other forums

It is recognised that commitment to collaboration, continuous improvement, and stakeholder feedback is essential to ensuring the reforms are effective and aligned with industry needs, fostering long-term success and sustainable impact

Monitor, adapt, and refine

Questions?

Scan the QR code with your device to submit a question.