Prescription Medicines Authorisation Branch Update

Mohit Khera
Medical Officer, Prescription Medicines Authorisation Branch,
Therapeutic Goods Administration.

Session overview

- PMAB – who we are and what we do
- Registration applications and performance
- International collaborations
- Real World Evidence
- Repurposing of medicines
- Product Information as a package insert for injectable products
- Other activities

What we do – Prescription Medicines Authorisation Branch

Clinical evaluation section A

Clinical evaluation section B

Clinical evaluation section C

Advanced and biological therapies

Clinical Evaluators Team

We evaluate and approve prescription medicines for use in Australia
but that's not all we do

- Public communications & consultations
- AusPARs & Decision Summaries
- eCTD management
- ACM and ACV secretariat
- Data analytics & reporting
- Pre-submission meetings & Case management
- Guidance on regulatory processes
- Regulation reviews to keep step with emerging therapies

and more!

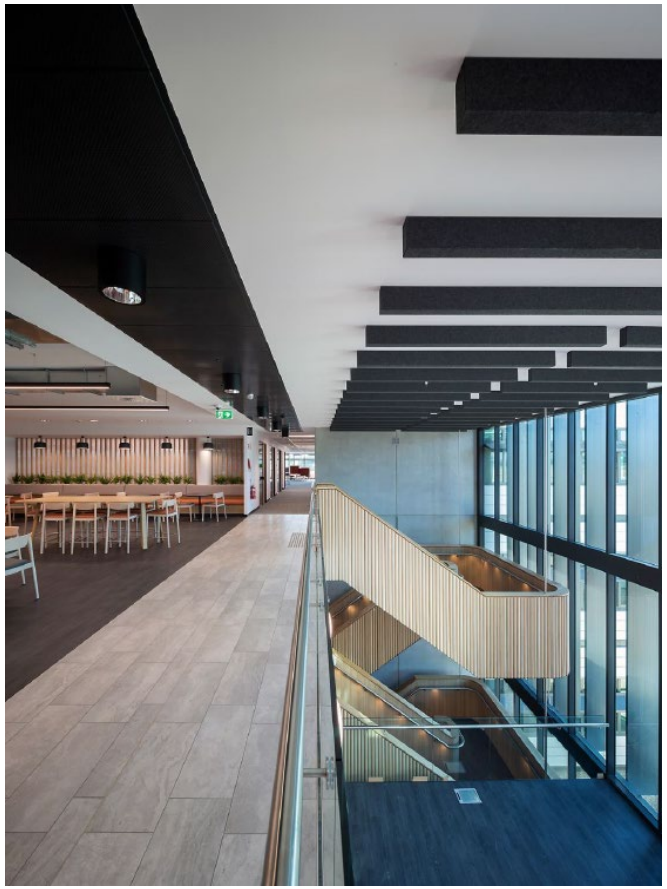
Pharmacist Evaluation Section

Application and advisory management section

Application entry, support and export section

Business systems review and reporting section

New buildings. New ways of working.



Leadership

Deputy Secretary, Professor Tony Lawler – commencing June 30

Tony is the Tasmanian Department of Health as the Chief Medical Officer and Deputy Secretary – Clinical Quality, Regulation and Accreditation.
Tony has extensive experience contributing to health policy and education on boards and committees including the Commission on Safety and Quality in Health Care, the Royal Australasian College of Medical Administrators, the Australian Medical Association and the National Health and Medical Research Council.

First Assistant Secretary, Nick Henderson

Nick has been an active leader at both the Department of Health and Services Australia.
Nick lead the rapid establishment of Australia's Vaccine Operations Centre, undertaking the role of Operations Commander for Australia's Vaccine Rollout and was key to ensuring collaboration and coordination between jurisdictions and the Commonwealth, including urgent outbreak responses.
Nick is now acting First Assistant Secretary of Medicines Regulation Division (MRD) within the Therapeutic Good Administration.

Assistant Secretary, Andrew Simpson

Andrew has been with the Department of Health since 2015.
Andrew has an extensive background in health policy. Prior to joining the PMAB team last year he worked on the Primary Care Reform Taskforce and before that worked on the Department's COVID-19 primary care response with responsibility for introducing telehealth Medicare items. He has also led the Medicare Review Taskforce

Recent highlights

- Rapid approval of COVID vaccines and treatment applications in response to new variants – 4 rolling submissions completed in short timeframes
- COVID vaccines moving to full registration
- Increasing international collaborations ACCESS workshares / Project Orbis
- Multiple first in class medicines approved

Sponsor	Vaccine	Indication	Approval date	Working days
Moderna Australia Pty Ltd	SPIKEVAX Bivalent Original/Omicron (elasomeran/imelasomeran) (Previously SPIKEVAX Bivalent Zero/Omicron (elasomeran/elasomeran 0- omicron)	Booster dose for adults aged 18 years and over	Provisionally approved 29 August 2022	49
Moderna Australia Pty Ltd	SPIKEVAX Bivalent Original/Omicron BA.4-5 (elasomeran/davesomeran)	Booster dose for individuals 12 years of age and over	Provisionally approved 17 February 2023	59
Pfizer Australia Pty Ltd	COMIRNATY Original/Omicron BA.1 (tozinameran and riltozinameran)	Booster dose for individuals aged 18 years and over	Provisionally approved 27 October 2022	41
Pfizer Australia Pty Ltd	COMIRNATY BIVALENT Omicron BA.4/BA.5 COVID-19 VACCINE (tozinameran and famtozinameran)	Booster dose for individuals 12 years of age and older	Provisionally approved 20 January 2023	23

A short plug for PMAB presentations this afternoon

Wednesday, June 7, 2023
4:30 PM - 5:30 PM

Transitioning from provisional to full approval

Dr Sarah Golding
Senior Medical Officer,
Clinical unit C (oncology and haematology),
Prescription Medicines Authorisation Branch,
TGA

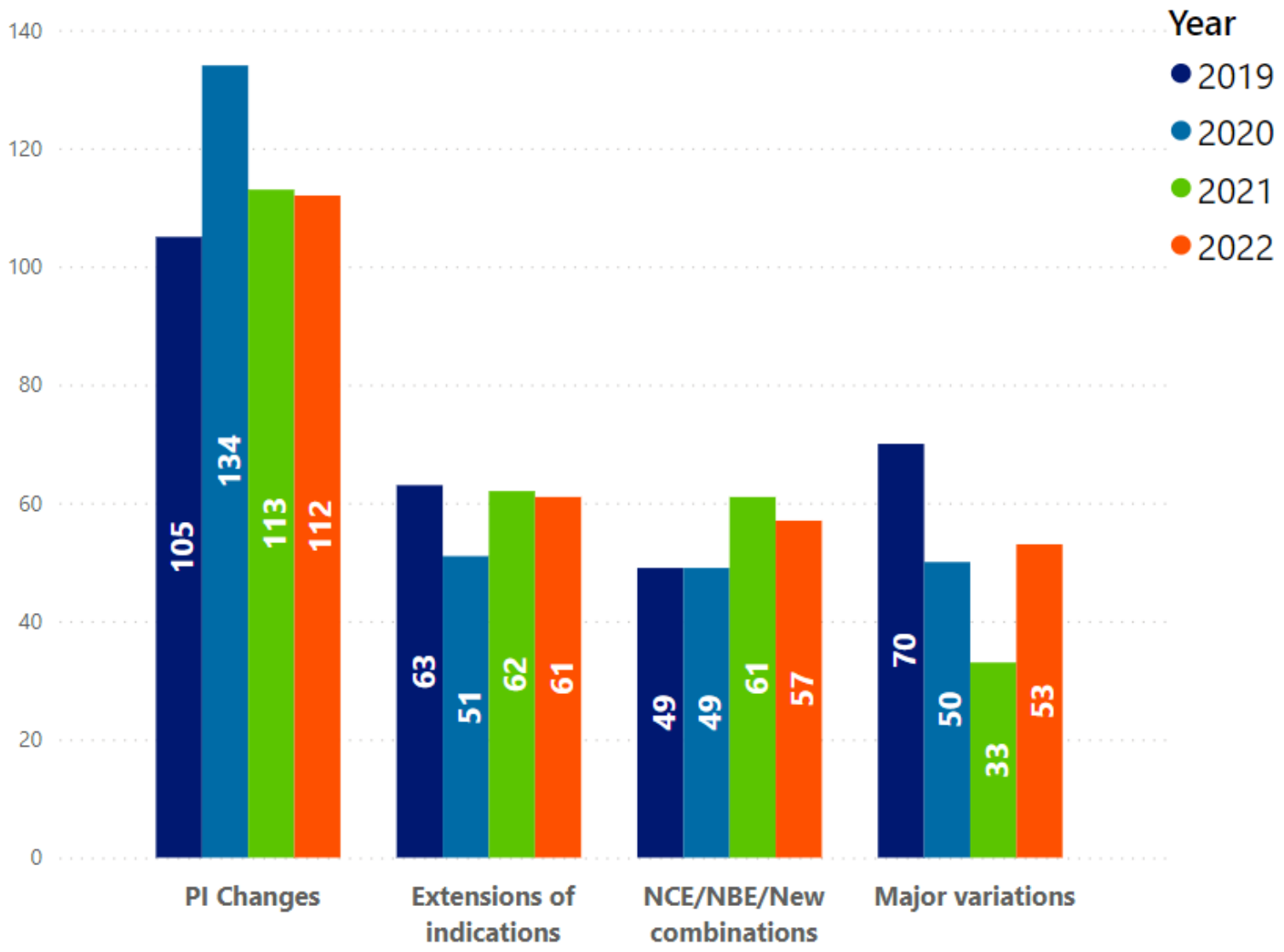
Transitioning from provisional to full approval

Biography

Dr Sarah Golding joined the TGA in 2013, and has seven years' experience in the regulation of oncology and haematology products. Prior to an MBBS at ANU, Sarah completed a BBiomedSci with an Honours year in biochemistry and molecular biology at Monash University.

Registration applications and performance

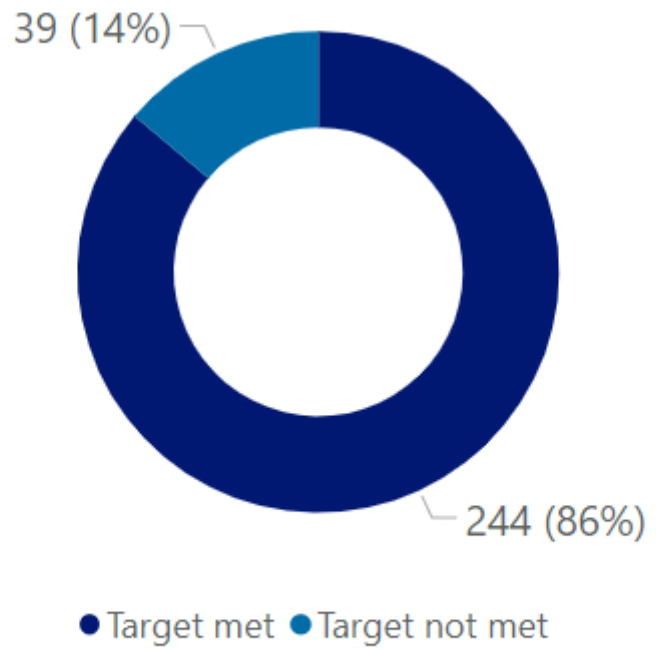
Cat1 and COR completions



Legislated days (255) being met in 2022

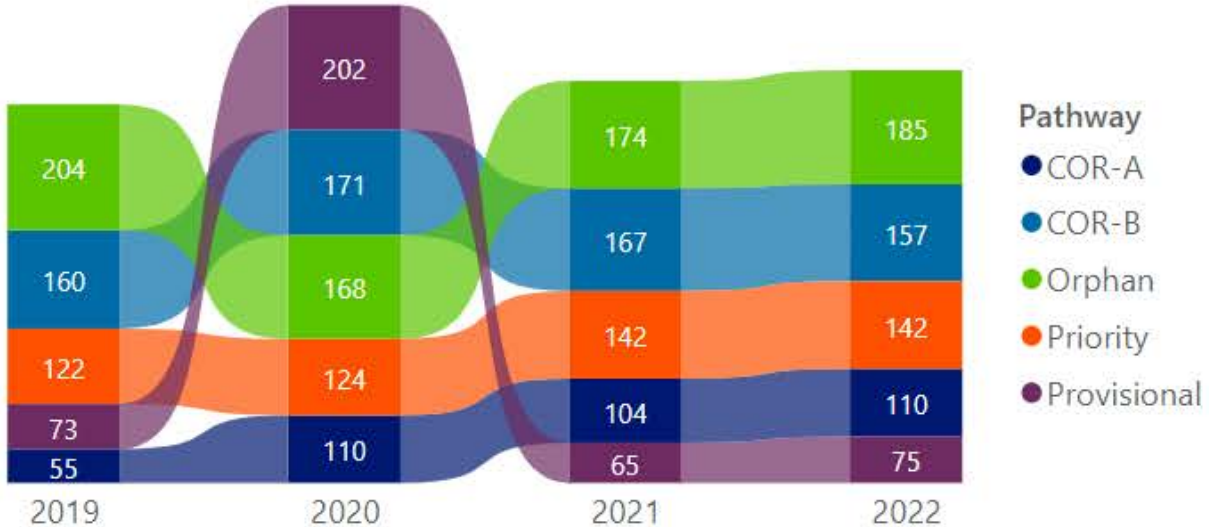
100.0%

Target days (220) being met in 2022

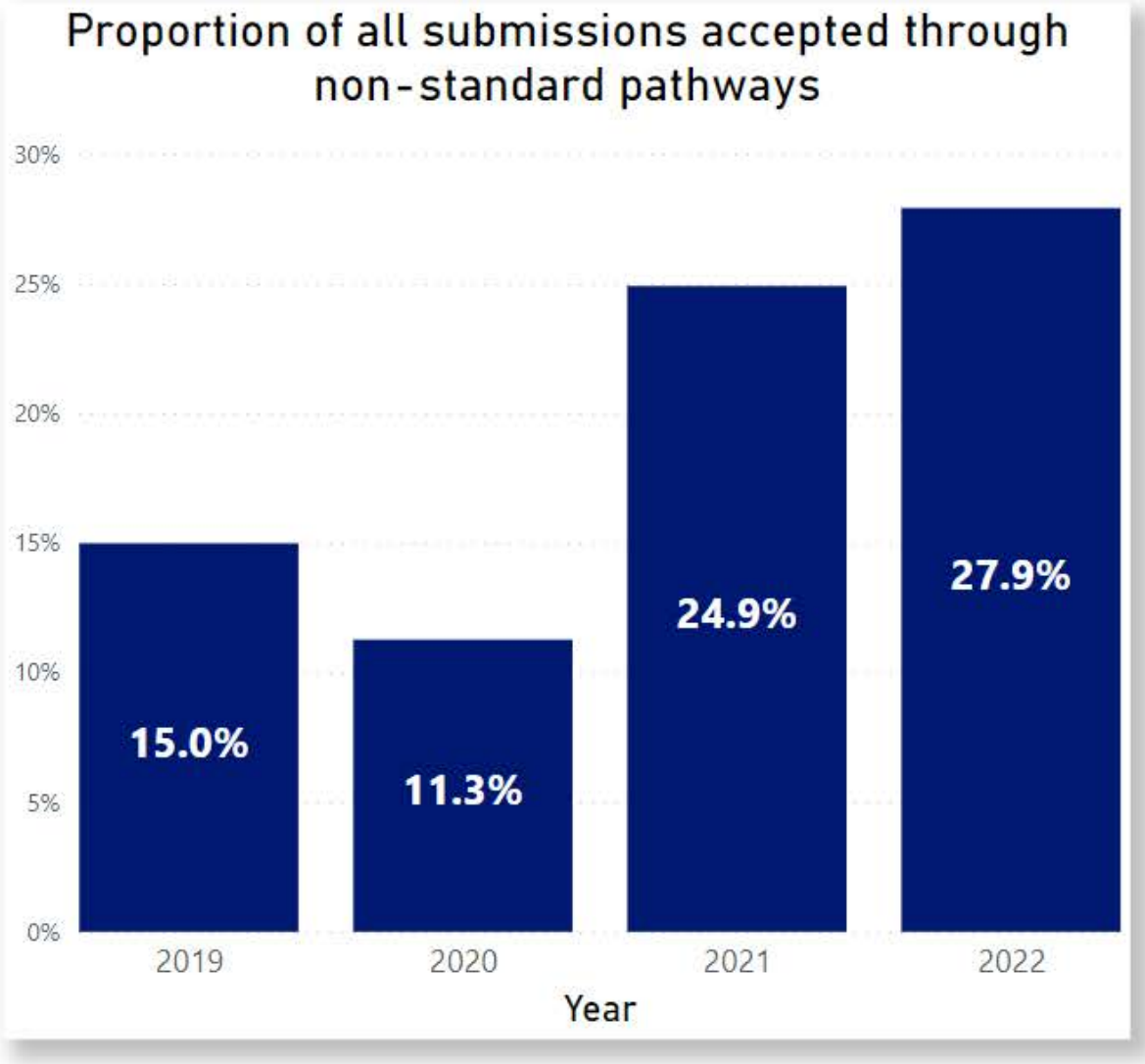


Pathway submissions

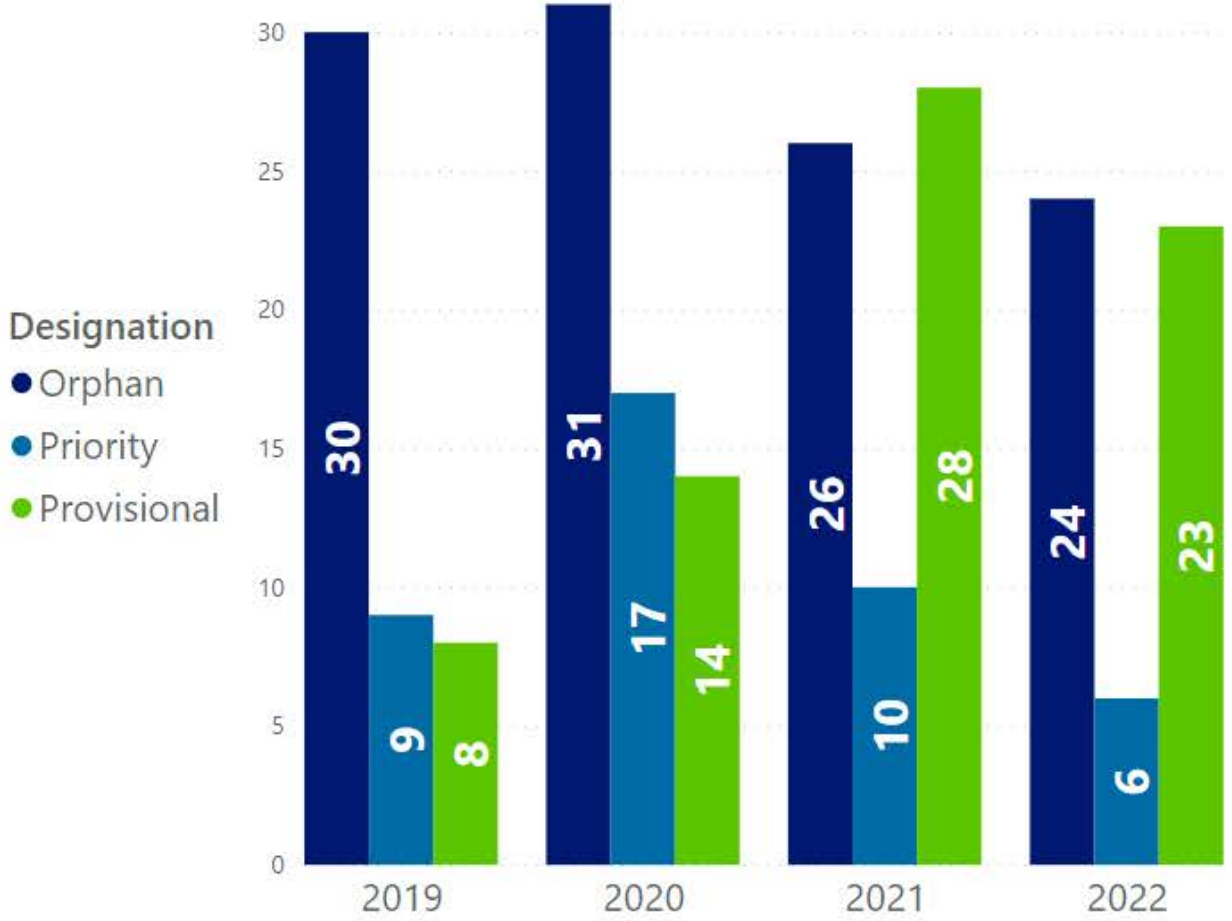
Median working days by pathway



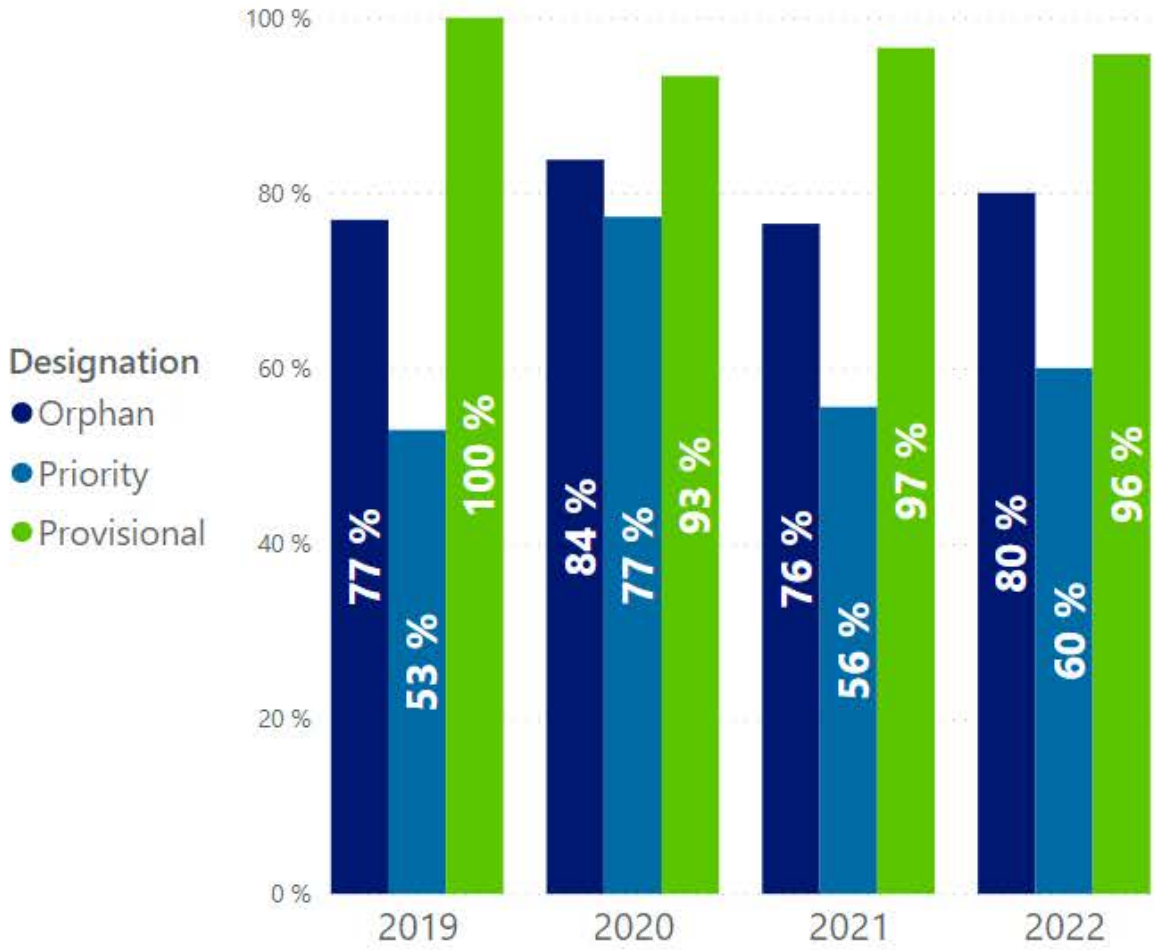
Proportion of all submissions accepted through non-standard pathways



Approved designations by year



Designation approval rate by year



International collaborations

Highlights

- Continued strong growth in international collaboration especially ACCESS work-sharing and Project Orbis
- Improved integration of frameworks across ACCESS agencies.
- TGA actively refining processes as experience is gained.
- Launch of Access biosimilars work-sharing expressions of interest are welcome.

ICMRA
International Coalition of Medicines Regulatory Authorities

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

PROJECT ORBIS

World Health Organization

Enhanced international collaboration for COVID therapeutic goods

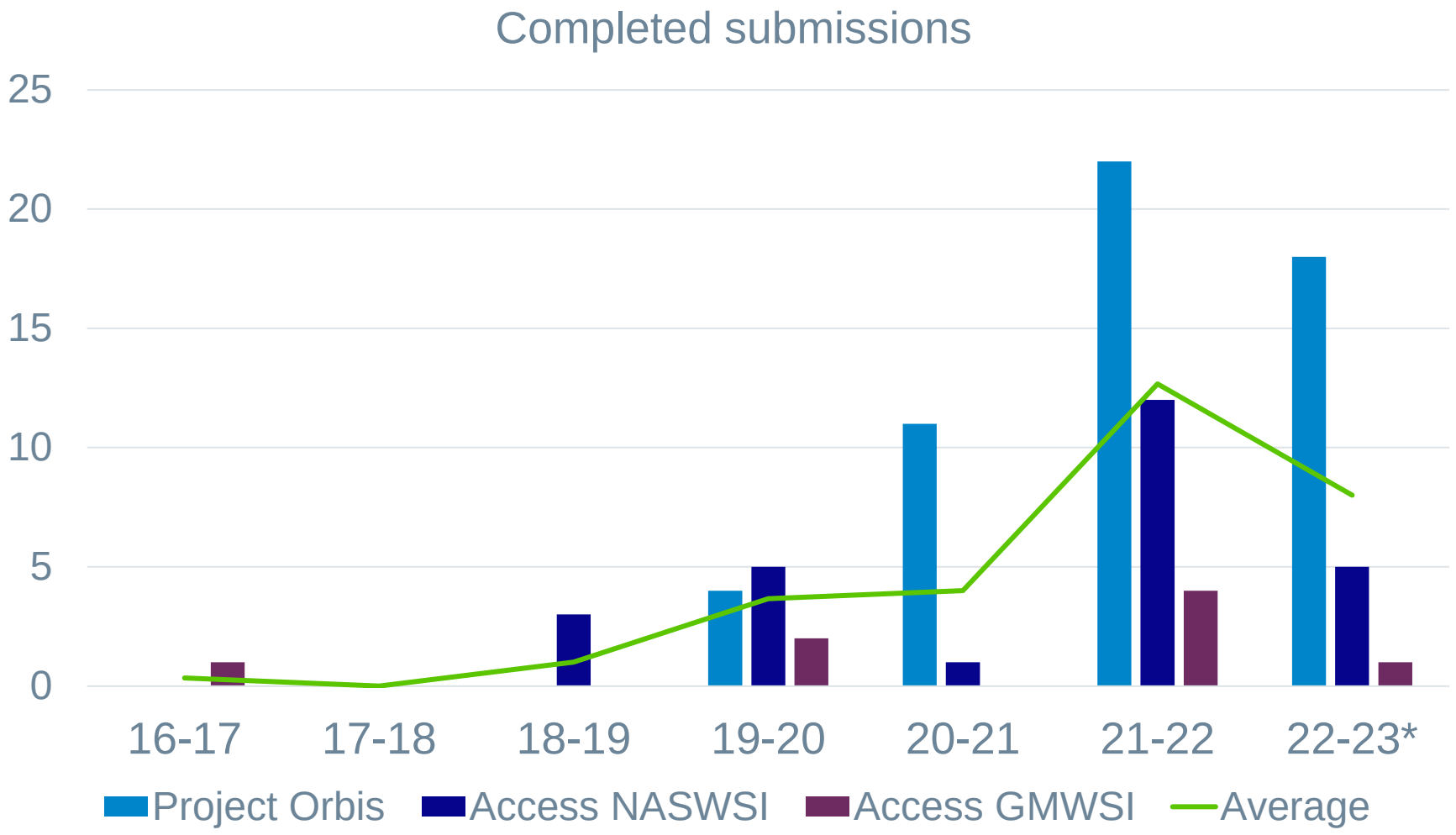
- **Regular updates on clinical trials and observational studies**
  - Early efficacy and safety signals
  - Especially important for a medium sized regulator in a country with lower COVID-19 caseload
- **Sharing of information on**
  - regulatory flexibilities, policies, pipelines, submissions and evaluations
- **Better collaboration** – better approach than independent duplication of effort!
  - COVID-19 has catalysed greater ongoing collaborations.

ACCESS and Project Orbis

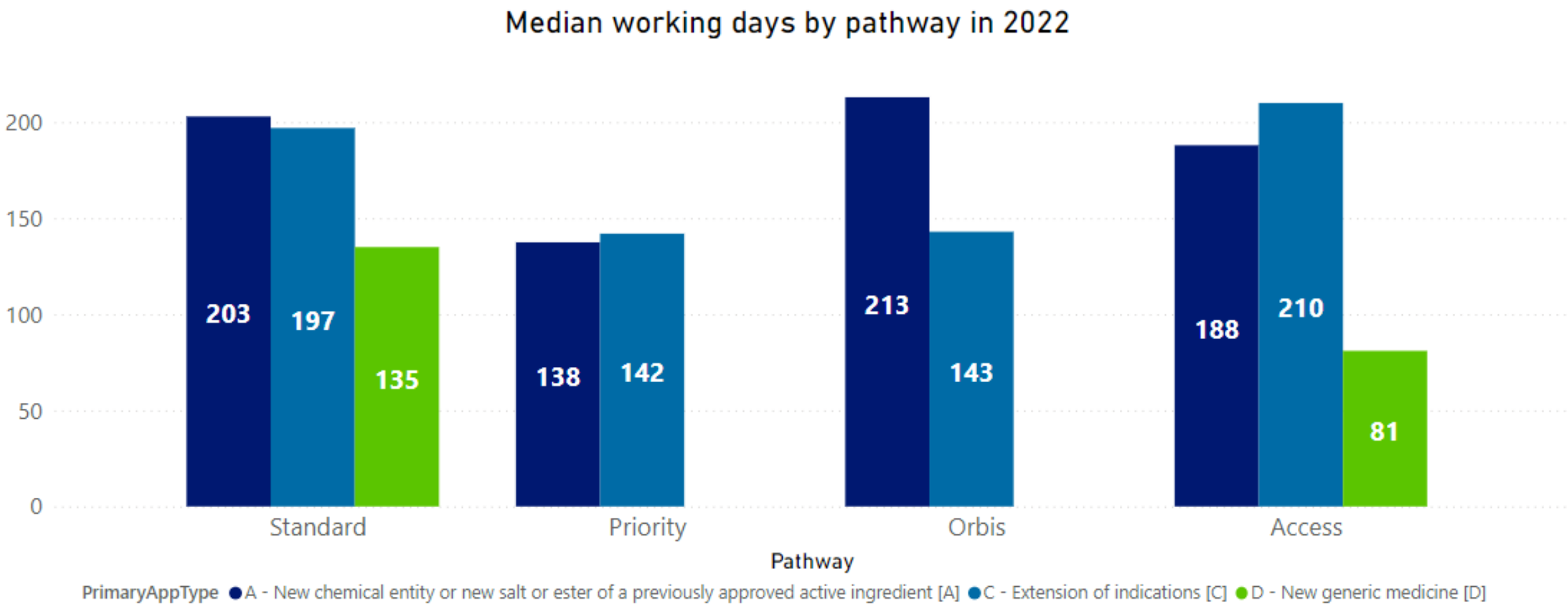
Number of completed international collaborations on submissions

	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23* (as of 22 May)	Total approved	On hand (under eval.)
Project Orbis	0	0	0	4	11	22	18	55	11
Access NASWSI	0	0	3	5	1	12	5	26	10
Access GMWSI	1	0	0	2	0	4	1	8	1

International collaborations – performance



Approval time comparison



Real World Evidence

Real World Evidence

Targeted consultation in 2022 of industry and consumer groups found our use of RWE and communication of how it is used in decision making could be improved.

- TGA has now adopted a similar definition of RWE to FDA:

  Data regarding the usage, or the potential benefits or risks, of a therapeutic good derived from sources other than traditional clinical trials

- Several EMA and FDA guidelines on RWE use have been adopted.
- Presubmission Planning Form now asks for details of RWE usage in sponsor submission
- RWE use described in AusPARs when used in regulatory decisions
- Central point for information about RWE and PROs on the TGA website:

  www.tga.gov.au/real-world-evidence-rwe-and-patient-reported-outcomes-pros

How are other regulators using RWE?

EMA

DARWIN EU: a catalogue of observational data sources for use in medicines regulation:

- providing high-quality, validated real world data on the uses, safety and efficacy of medicines
- addressing specific questions by carrying out high-quality, non-interventional studies

FDA

CURE-ID: A dedicated initiative designed to capture real-world clinical outcome data to advance drug repurposing and inform future clinical trials for diseases of high unmet medical need.

Other regulators

MHRA, Health Canada and PDMA Japan have released various statements and guidance documents on RWE to facilitate greater use in regulatory decision making.

Repurposing of medicines

Repurposing of medicines

Repurposing of medicines is the process of identifying potential new therapeutic uses (or 'indications') for older medicines through new research and evidence.

This includes indications where a public health benefit has been identified, including indications that are already approved overseas or for a less common disease.

Why repurpose medicines?

- Address gaps in therapeutic options for a range of health conditions and patients
- Give more patients access to effective medicines as off-label prescribing not consistently utilised e.g., in rural areas
- Reduce medico-legal risks to prescribers by increasing the number of approved treatment options available for use.
- Target medicines for which a significant public health benefit has been identified but there is little or no commercial incentive for a sponsor to pursue regulatory approval including PBS.

February 2021 to May 2023

Key points from 2022 consultation responses

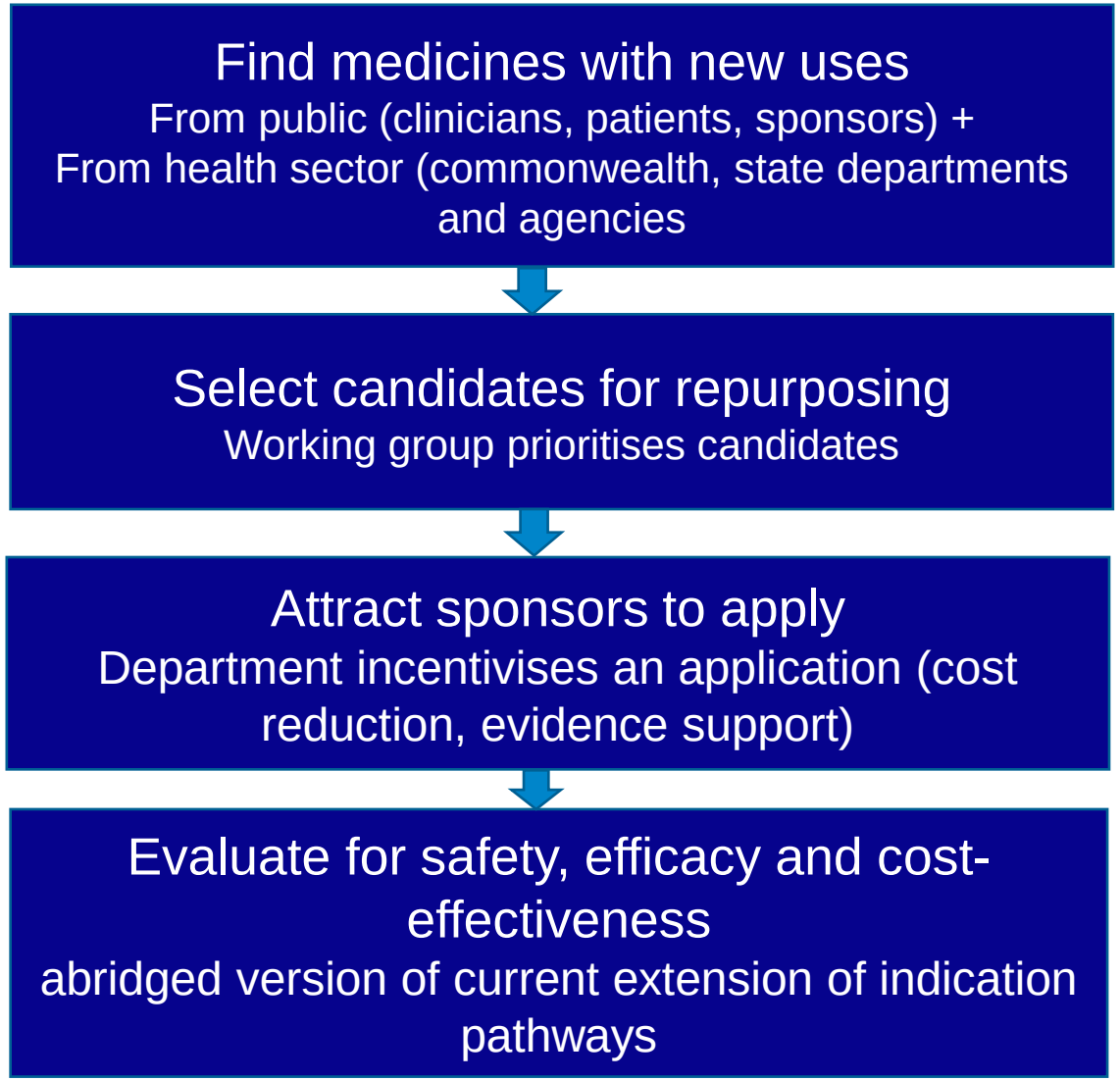
- Repurposing medicines and reducing regulatory burden welcomed
- All stakeholders want early involvement to ensure patient voice, safety, efficacy, commercial viability and regulatory factors considered at outset
- Clear guidance and criteria to be set by the Department, including RWE usage
- Strong sentiment for ‘patient voice’, unmet need, patient care and QoL was raised

Budget
2023–24

BUDGET MEASURES
BUDGET PAPER NO. 2

- $10.1 million over 4 years from 2023–24 for the Therapeutic Goods Administration to assist medicine sponsors repurpose targeted medicines by expanding approval for their use in Australia.

Framework for medicines repurposing



Going forward

- Continue to consult as we develop framework and processes
- Appoint Reference Working Group
- Select viable candidates
- Recruit dedicated team

Product Information as a package insert for injectable products

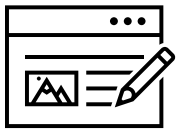
Current status

- The TGA currently requires injectable products to contain a hard copy of the Product Information (PI) as a package insert. This is a condition of registration imposed under section 28(2B) of the Act

SPECIFIC CONDITIONS APPLYING TO THESE THERAPEUTIC GOODS

2. The Product Information applying to these therapeutic goods must meet the TGA's approval at all times. Any proposed changes to the approved text of the PI, including safety related changes, must be submitted to, and be approved by, the TGA prior to distribution.

For all injectable products the Product Information must be included with the product as a package insert.



Safety information in the PI is updated regularly. However, there is a lag time between safety information being updated and that information being added to the hard copy PI included in the injectable packaging.

Emerging concerns and industry feedback

- Outdated safety information - The hard copy PI does not contain the latest safety information
- Larger packaging requirement - The packaging may be larger to accommodate the hard copy PI
- Industry and other stakeholders have voiced concerns - Cost impact, supply chain issues, challenges with updating the hard copy PI, and the environmental impact of supplying a hard copy PI with injectable products

TGA addressed some issues recently:

- Some exemptions provided for vaccines to be supplied without a hard copy PI
- Minimised disruption to the local packaging process and supply chain

Public consultation

July-October 2022.
Details on www.tga.gov.au

Based on the feedback, TGA examined the usefulness of the hard copy PI in injectable products administered by Healthcare Professionals (HCPs).

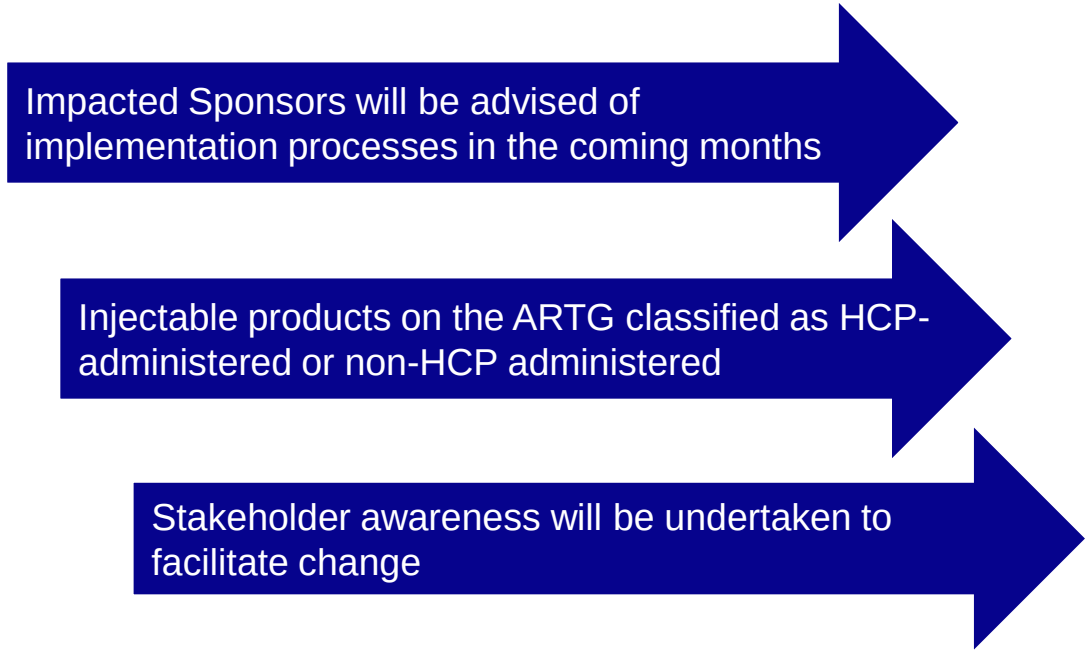
Non-HCP administered injectables were not in scope.

Decision

The TGA will cease the standing practice of imposing a condition of registration under subsection 28(2B) of the *Therapeutic Goods Act 1989* that the PI 'must be included with the product as a package insert' for injectable products that are administered by Healthcare Professionals.

This change will come into effect from 1 September 2023.

- Does **not** extend to non-HCPs administered injectable products.
- Does **not** remove the option for the Delegate to determine that a package insert is required for a specific product and to advise the sponsor of this decision.



If you have any questions please email boxedinjectables@Health.gov.au

Update on eCTD transition for prescription medicines

May 2023 – eCTD-Only Stage 3

- Prescription medicine data including master files only accepted in eCTD format.
- eCTD now mandated for all new activities associated with prescription medicine regulation.
- Planning underway to reform AU Module 1 and Regional eCTD Specification towards eCTD v4.0.

Website references

TGA website	www.tga.gov.au
RWE and PROs on the TGA website	www.tga.gov.au/real-world-evidence-rwe-and-patient-reported-outcomes-pros
TGA public consultation	https://www.tga.gov.au/resources/consultation/consultation-product-information-package-insert-boxed-injectables
Boxed Injectables contact	boxedinjectables@Health.gov.au
Repurposing of medicines updates	www.tga.gov.au/medicines-repurposing-program-support-new-clinical-uses-existing-medicines
Exports	www.tga.gov.au/how-we-regulate/import-and-export/export
Contact us	tgainfo@health.gov.au

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

Want to chat with me further? Come visit us.

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration