

Medicines Repurposing Program

Dr Jessica Tidemann

Senior Medical Officer

Prescription Medicines Authorisation Branch

Department of Health and Aged Care, TGA



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Outline

Program overview

Candidate identification

Candidate selection

Program progress update

What's next?



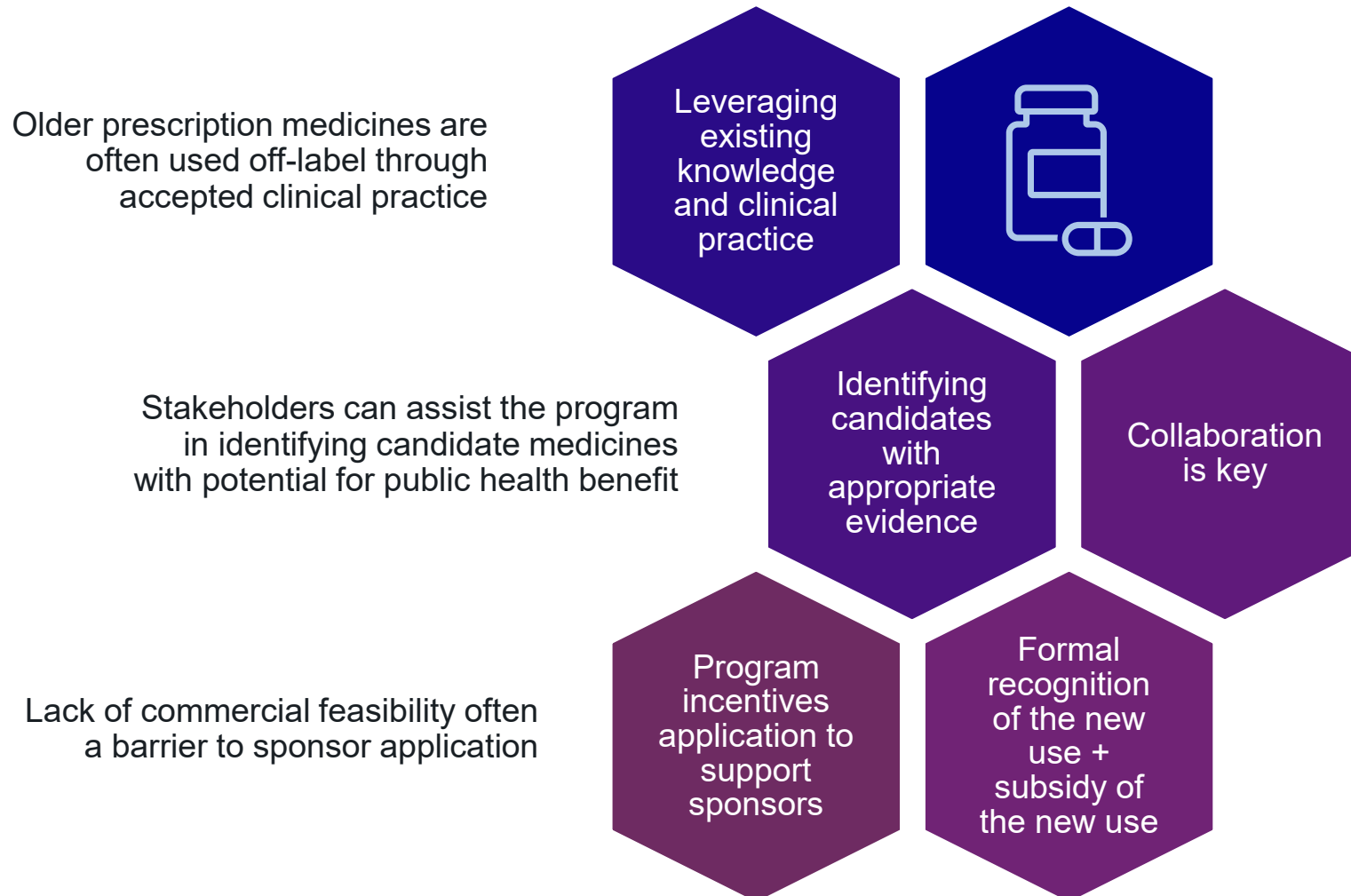
Program overview

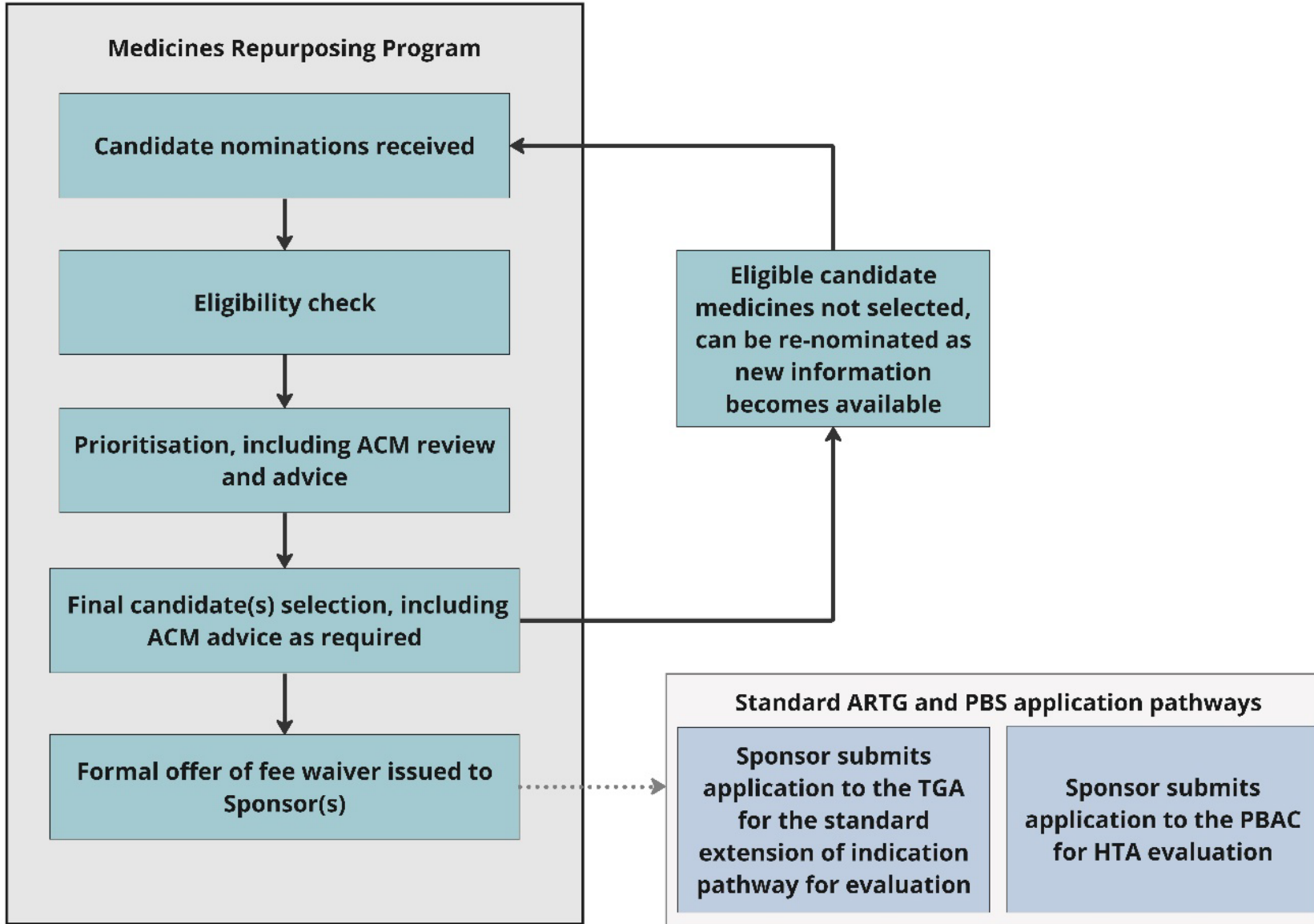
The Medicines Repurposing Program (MRP) aims to improve patient access to medicines in Australia by supporting the regulatory recognition and subsidy of new therapeutic uses for existing medicines.

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



Repurposing of medicines in Australia





Program eligibility criteria



Prescription medicine registered
in the ARTG

and



New, distinct indication

Identifying candidate medicines



Focus on medicines no longer under patent protection



Existing evidence base



Demonstrated treatment or access gap



Clear public health benefits

Nominating a medicine



Highlight existing treatment or access barriers and how this new use will improve them



Outline evidence of efficacy and established clinical use in Australia for new indication



Include details of approval by Comparable Overseas Regulator(s) *(if applicable)*



Engagement with existing sponsor(s)



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Medicines Repurposing Program - Nomination form

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You use this form to nominate medicines for the Medicines Repurposing Program (MRP) if you are a:

- pharmaceutical company registered in Australia
- not-for-profit organisation that is Australian based, such as charities or patient advocacy groups, clinical groups, academics, researchers
- individual member of the public, with a particular interest in medicines repurposing.

The information provided on this form will be used to assess for eligibility, feasibility and prioritisation of the candidate medicine for the MRP. You are encouraged to review the [eligibility criteria](#) before completing the nomination form.

Nominations will be assessed in batches on a rolling basis to allow review of eligible medicines at the Advisory Committee on Medicines (ACM) meetings, which are held at regular intervals.

Do not include any personal identifying information of individual patients. Any commercial-in-confidence information that may be included in your proposal should be clearly identified as such.

For any enquiries regarding the form please email mrp@health.gov.au

Nomination form

1 Nominator details 2 Medicine details 3 Additional information 4 Preview 5 Complete

This form, when completed, will be classified as 'For official use only'. For guidance on how your information will be treated by the TGA see: <https://www.tga.gov.au/treatment-information-provided-tga>

Nominator details

Name (individual or group/organisation) (mandatory)

Email address (mandatory)

Alternate email address

[Next Page >](#)

Assessment and prioritisation of eligible candidate medicines

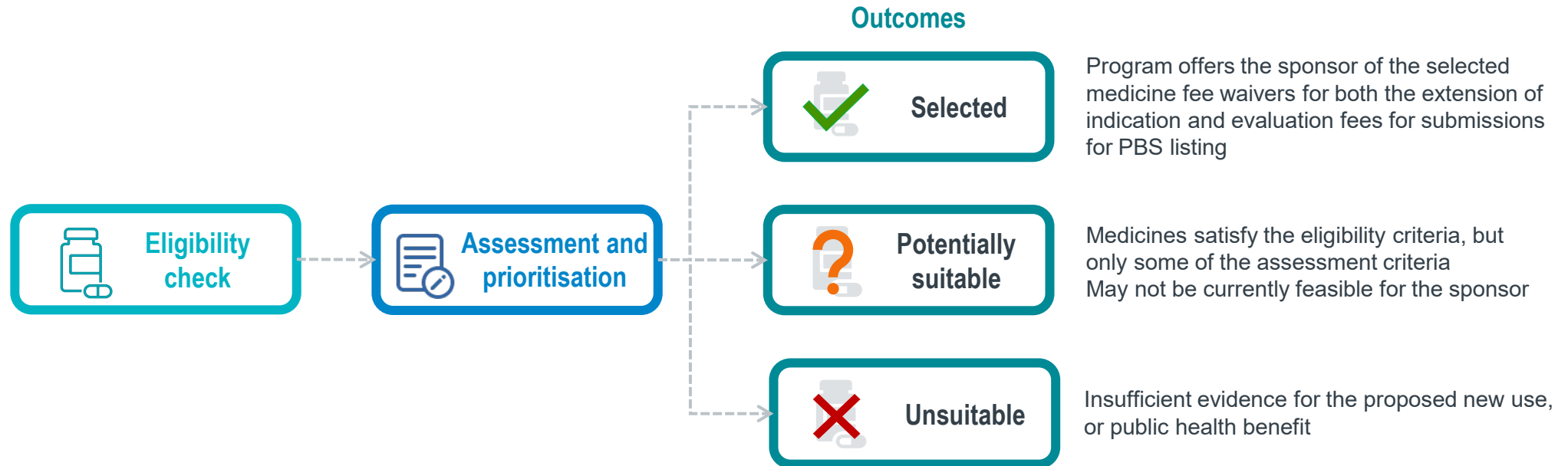
Assessment and prioritisation considers multiple factors:

- Public health benefit
- Existing evidence base
- Constraints or barriers to application
- Advice from the ACM
- Sponsor support

Early involvement of registered sponsors to determine feasibility of program participation is crucial



Candidate selection



Program progress update

Program opened to receive nominations on 1 March 2024

Assessment of first batch of candidates, with ACM advice, has taken place

Progression of feasible candidates

Challenges and observations so far



Criteria for
prioritisation



Engagement of and
feasibility for current
sponsors

Opportunities for non-
pharmaceutical
sponsors

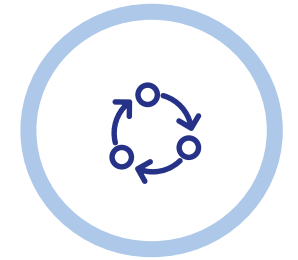


Potentially intensive
process for the
TGA (dedicated team)

Also for sponsors



Communication
and managing
expectations



New program
requiring ongoing
review and
refinement

Collaborative, adapting approach



Engagement with stakeholders to identify potential candidates



Continuing discussions to facilitate improved access for patients and address potential barriers



We expect process refinements over time based on feedback to best ensure the program meets its goals



Member of **Medicines Repurposing International Network (MeRIT)** to foster collaboration with other repurposing initiatives *14 organisations, spanning 8 countries and the European Union*

What's next?



Continued **communications and awareness** activities to encourage nominations of potential candidates

Utilise insights from the initial implementation to **refine criteria and processes**

Engage with the MRP



Feedback & insights

As a new program, we expect to have continuing discussions and remain open to feedback.



Get in touch

You can reach out to the Program team with questions.



Learn more

You can join our mailing distribution list for regular Program updates.

MRP@health.gov.au

Information and resources



[tga.gov.au](https://www.tga.gov.au) –
Establishment of
the Medicines
Repurposing Program



MRP@health.gov.au



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