Information session:
Medicines Repurposing Program

Natasha van de Brug
Program Manager
Prescription Medicines Authorisation Branch, TGA

Dr Jess Tidemann
Medical Officer
Prescription Medicines Authorisation Branch, TGA

12 March 2024

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

Welcome

Housekeeping

This webinar is only being recorded for data and analytics purposes.

Closed captions are available

Activate it with the speech bubble icon on the bottom left of your screen

Difficulties with sound?

Check your settings located under

Audio & Video located top of your screen

You can also call to join the webinar on the details below.

Dial: 02 9338 2221 (+61-2-9338-2221)

Access code: 2650 335 4481

Accessing Slido

Through the Slido application in Webex

- Click on the **Apps** icon
- Select **Slido**
- Open the poll tab to complete survey when prompted

Using the QR code

Scan the QR code to access Slido from your mobile device

Information session:
Medicines Repurposing Program

Natasha van de Brug
Program Manager, Prescription Medicines Authorisation Branch, TGA

Dr Jess Tidemann
Medical Officer, Prescription Medicines Authorisation Branch, TGA

12 March 2024

Session outline

- What is medicine repurposing?
- Goals of the program
- How the program works
- Identifying candidate medicines
- Progressing eligible candidate medicines
- Decision outcomes

Natasha van de Brug

Program Manager

Prescription Medicines Authorisation Branch, TGA

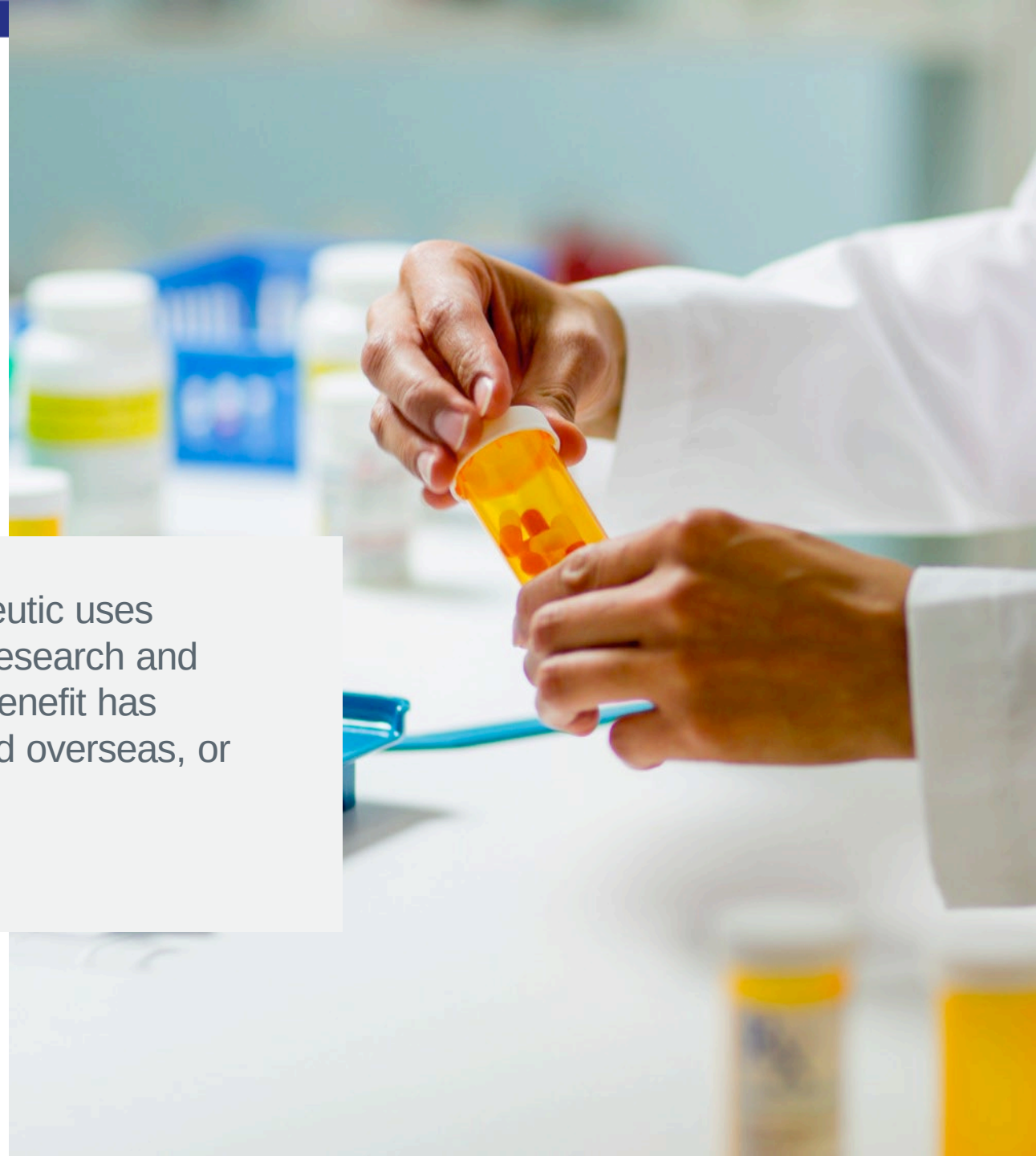
Dr Jess Tidemann

Medical Officer

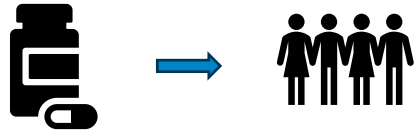
Prescription Medicines Authorisation Branch, TGA

Repurposing of medicines

The process of identifying potential new therapeutic uses ('indications') for older medicines through new research and evidence. This includes where a public health benefit has been identified and indications already approved overseas, or for a less common disease.

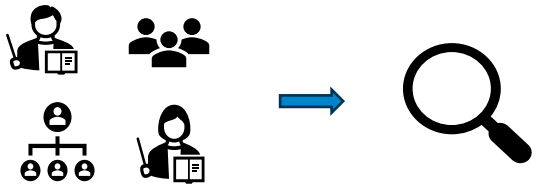


Repurposing of medicines in Australia



Older prescription medicines are often used off-label through accepted clinical practice

Can lead to inequity of access for patients

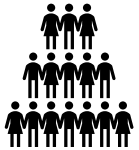


Stakeholders can assist the program in identifying candidate medicines with potential for public health benefit

Identifying candidates with appropriate evidence is key

Lack of commercial feasibility often a barrier to sponsor application

Program incentivises application to support sponsors seeking formal recognition of the new use



Improve patient access

Identifying candidate medicines

Find new uses for existing medicines

Collaborative approach inviting nominations from stakeholders

Focus on off-patent medicines, although opportunities for on-patent medicines may also exist

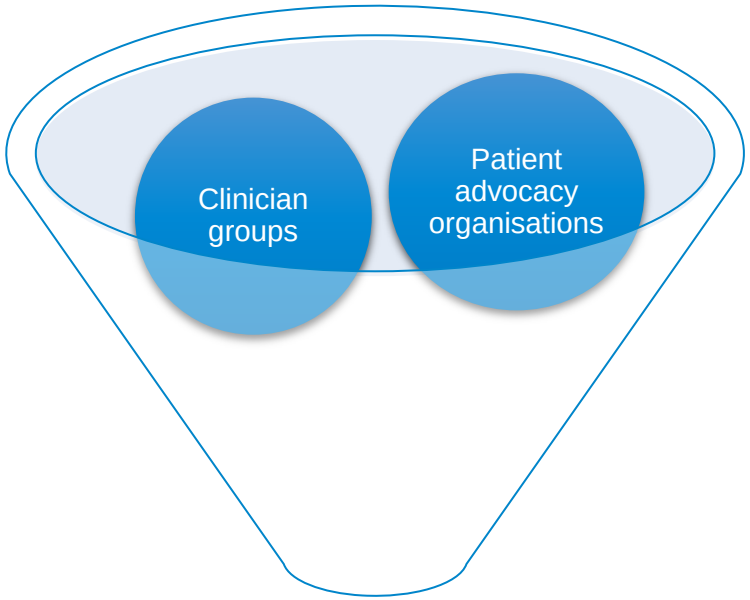
Program targets medicines for which a significant public health benefit has been identified but with little or no commercial value to a sponsor

Eligibility criteria

Prescription medicine registered on the ARTG

AND

A new, distinct indication



Eligibility assessment

Eligible medicines progress for prioritisation and potential selection

Nominating a medicine

Medicine details including proposed new use (indication) summary

Evidence of established clinical use in Australia

Details of registration of proposed new indication by comparable overseas regulators

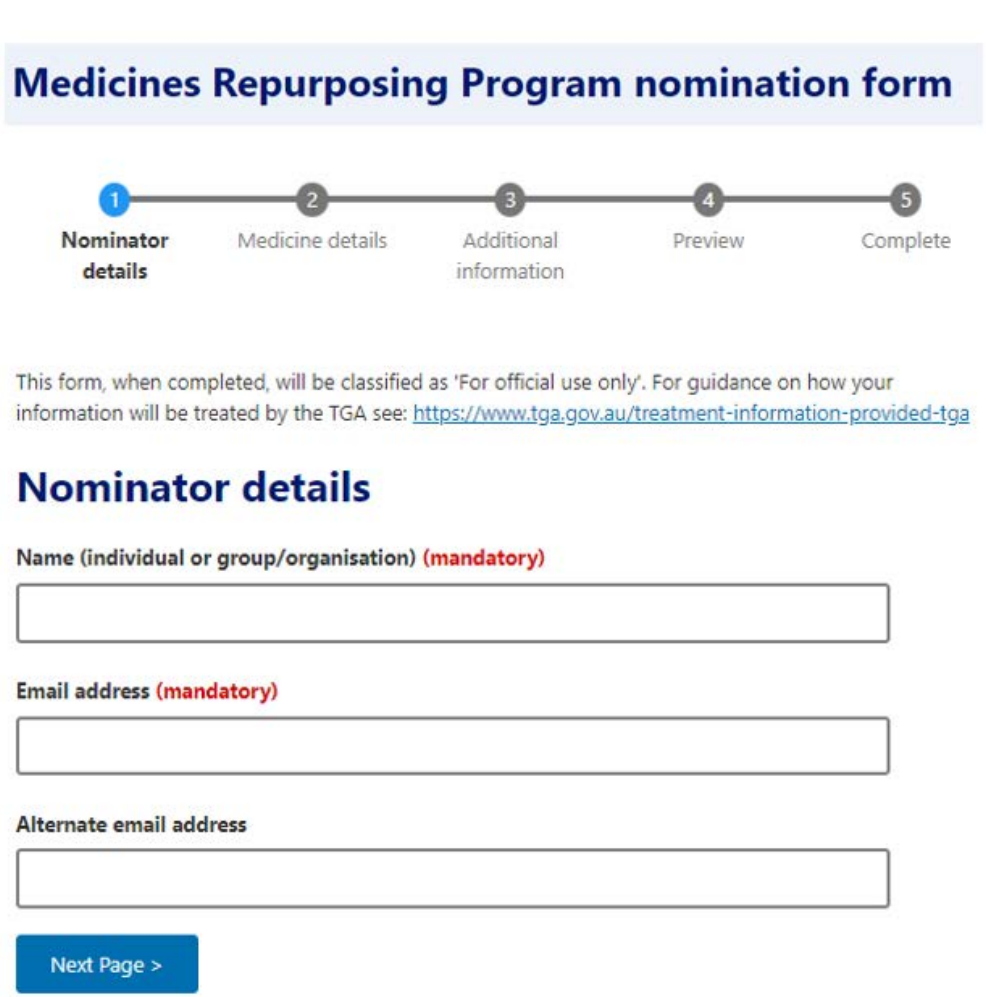
Sponsor contact

Details of any significant safety concerns

Medicines Repurposing Program nomination form

Nominating a medicine

tga.gov.au



Progressing eligible candidate medicines

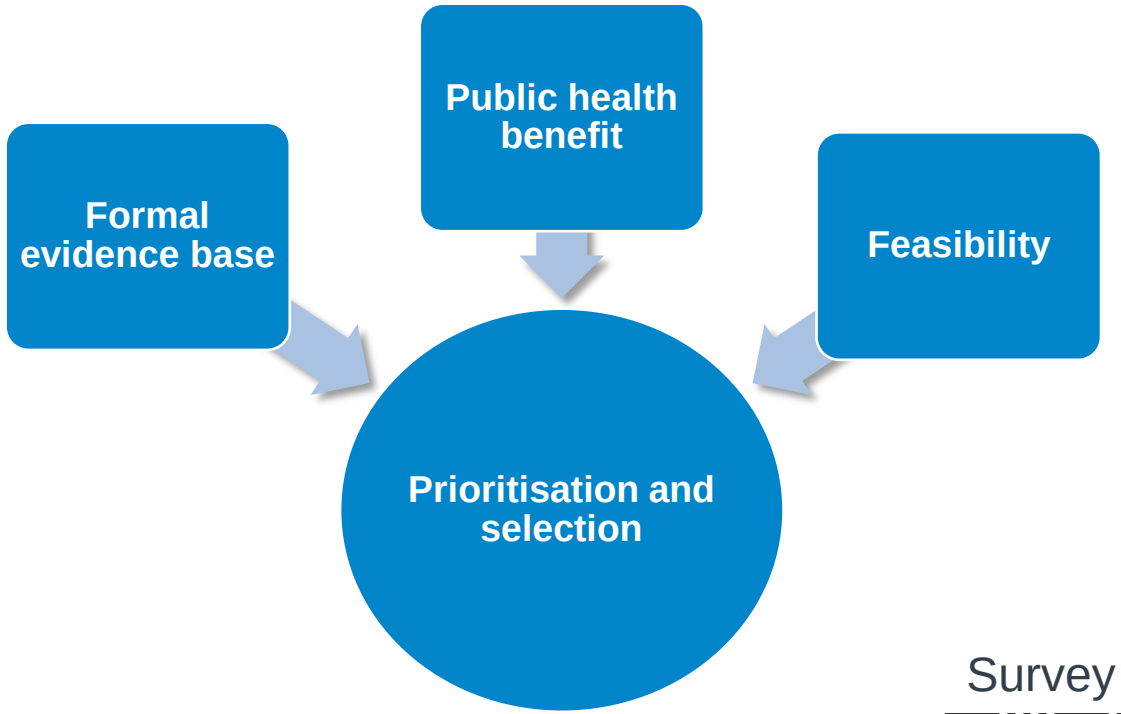
Assessment and prioritisation

Early involvement of registered sponsors to determine feasibility of program participation

Assessment of evidence base to support proposed new use – clinical guidelines, literature, approval by a comparable overseas regulator

Feasibility of regulatory/subsidy applications – constraints/barriers and ways to overcome them considered

ACM advice regarding potential public health benefit



Survey

Decision outcomes

Selected for repurposing

Sponsor of selected medicine is offered full fee waivers for TGA extensions of indication application and evaluation fees and PBAC application fee

Selection for repurposing does not guarantee TGA approval or PBS listing (subsidy) of the new use

Applications will be evaluated by the TGA and PBAC as per standard pathways

Sponsors will remain liable for pharmacovigilance and other post-market obligations and responsibilities as per standard pathways

Potentially suitable for repurposing

Medicine partially satisfies assessment criteria; may have limited formal evidence

Currently may not be feasible for the sponsor

May be considered for future selection

Unsuitable for repurposing

Insufficient evidence for the proposed new use, or its public health benefit

Can be re-nominated should new information become available

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 **Me**dicines **R**epurposing **I**nternational Ne**t**work (MeRIT) to foster collaboration with other repurposing initiatives
14 organisations, spanning 8 countries and the European Union

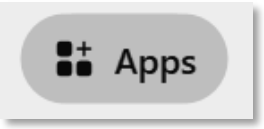
Q&A

1. Does a medicine need to be currently listed on the PBS?
2. Would black box warnings on the medication affect its eligibility?
3. What is the level of evidence required for a repurposing nomination? (e.g. a clinical trial, a pilot, or real-world evidence)
4. How will the program address off-label use of medicines in children?
5. For an off-patent product, how does the nominator approach some generic sponsors being interested in the indication/population and others not?
6. Will medicine sponsors have the opportunity to provide pre-ACM comments for medicines nominated by other stakeholders?

Survey

How did we go?

Take a moment to complete our survey



Use the app in Webex

Use the QR code

Information and resources

Establishment of the Medicines Repurposing Program

MRP@health.gov.au

Stay connected

Subscribe to updates

Social media

LinkedIn

X (Twitter)

YouTube

Instagram

Facebook

www.tga.gov.au/about-tga/social-media

www.tga.gov.au/news/subscribe-updates

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration