



Australian Government  
Department of Health

# **POST-MARKET REVIEW OF OPIOID DEPENDENCE TREATMENT PROGRAM MEDICINES (ODTP PMR) STAKEHOLDER CONSULTATION FORUM**

---

Thursday, 24 February 2022, 2:30 – 5pm AEDT

ODTP PMR website - [www.pbs.gov.au/info/browse/reviews](http://www.pbs.gov.au/info/browse/reviews)

Contact for the ODTP PMR - [ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au)



# Agenda for the Stakeholder forum

---

- Welcome and Housekeeping
- Introduction to the ODTP PMR
- Poll Questions
- Discussion Questions (including 10 minute break)
- Question and Answer Session
- Conclusion



## Housekeeping

---

- Please raise your hand to speak during the discussion questions using the “hand up” button located either on the top right of the screen (desktop app) or in the floating menu bar on the bottom of the screen (browser).
- Please state your name and the capacity in which you are attending today.
- If time runs out for discussions, additional input or comments regarding the discussion questions can be submitted via email ([ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au)) by 5pm Thursday 3 March 2022.
- You may also submit questions and contributions through the chat function.



## Post-market Review (PMR) of PBS subsidised medicines

---

The overarching aim of a PMR is to ensure the continued safe, effective and cost-effective use of Pharmaceutical Benefits Scheme (PBS) medicines. PMRs seek to achieve five main goals:

- improved patient safety
- ongoing viability of the PBS
- a better understanding of medicines utilisation
- ongoing cost-effectiveness
- quality use of medicines and education for patients and prescribers.



## Post-market Review Framework

---

PMRs are conducted according to the PMR Framework, agreed with industry.

The Framework sets out the steps that are to be followed throughout the Review, including when and how stakeholders are to be consulted.

The Framework is available at:

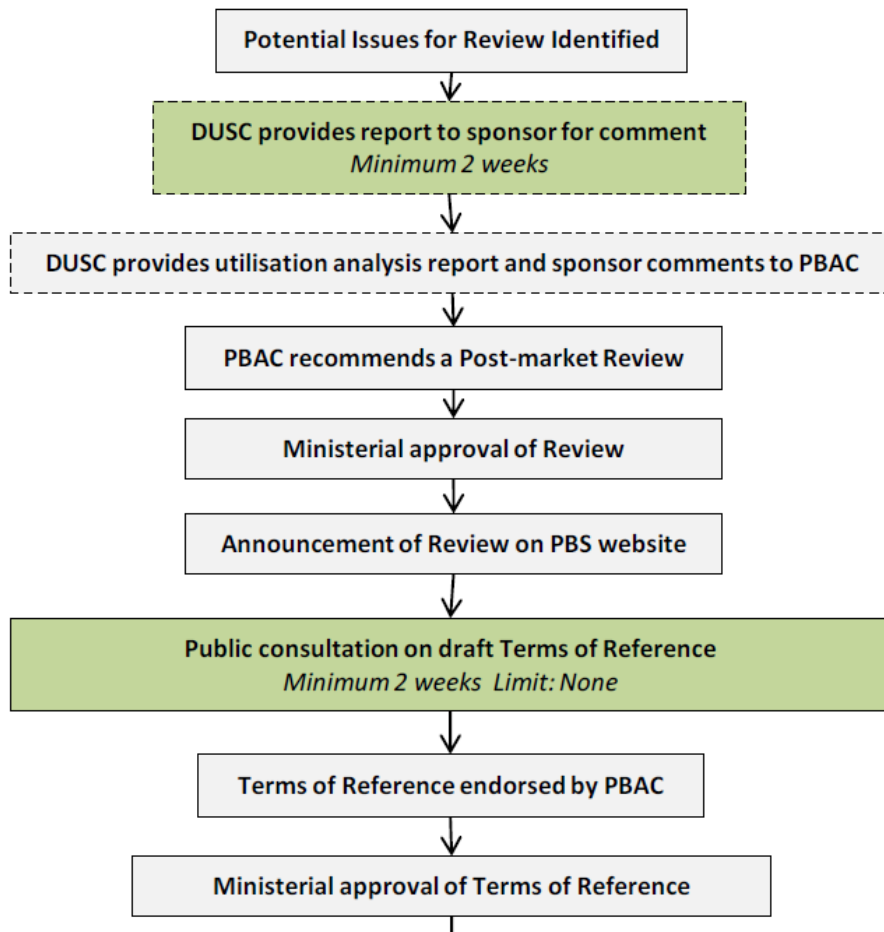
<http://www.pbs.gov.au/info/reviews/subsidised-medicines-reviews>

The Terms of Reference for the ODTP PMR can be viewed at:

<https://www.pbs.gov.au/info/reviews/post-market-review-of-opiate-dependence-treatment-program>



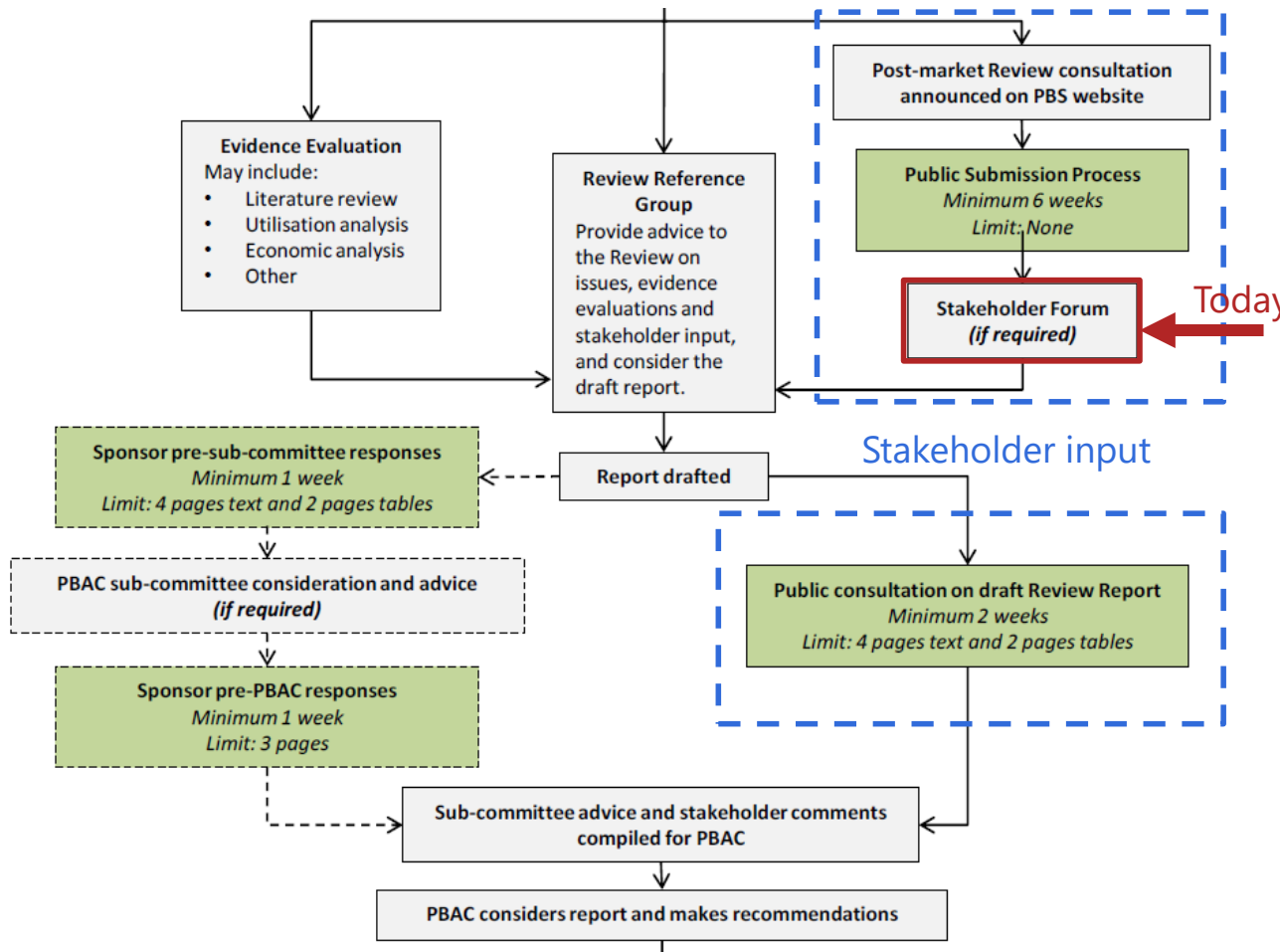
# Post-market Review Framework



- The Pharmaceutical Benefits Advisory Committee (PBAC) recommends new medicines for listing on the PBS. No new medicine can be listed unless the committee makes a positive recommendation.
- The Drug Utilisation Sub Committee (DUSC) of the PBAC assesses estimates on projected usage and financial cost for medicines, collects and analyses data on actual use, and provides advice to the PBAC.



# Post-market Review Framework



- To complement this Forum, a market research company will be conducting additional targeted consultation with consumers of opioid dependence treatment medicines.
- If you are interested in participating, please email [ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au)



## Outcomes of Post-market Reviews

---

Findings from the PMR are used to provide advice to the PBAC, which in turn provides advice to the Minister for Health.

Outcomes of PMRs vary, but may include:

- changes to PBS restrictions e.g. clarity of eligibility criteria for access to Opiate Dependence Treatment (ODTP) medicines
- addressing gaps in prescriber education and research
- improving awareness of the safety profile of in-scope medicines
- changes to cost of PBS subsidy following a review of cost-effectiveness e.g. how ODTP medicines are listed on the PBS

ODTP PMR - the final report to the PBAC and the Minister for Health is expected to propose improved service delivery arrangements for access to opioid dependence treatment (ODT) medicines through the PBS.



# Opioid Dependence Treatment Program Overview

---

- There are currently three medicines available for the treatment of opioid dependence under the PBS ODTP.
- These medicines are:
  - ❖ Buprenorphine (sublingual tablets and modified release injections),
  - ❖ Buprenorphine with naloxone (sublingual films)
  - ❖ Methadone (oral liquid)
- The PMR is limited to the medicines currently listed on the PBS and available under the ODTP.



## Opioid Dependence Treatment Program Overview cont.

---

- Currently, the Australian Government pays the full cost of medicines available under the PBS ODTP.
- State and territory governments are responsible for the administration of opioid dependence treatment programs i.e. approving the participation of prescribers, dispensing sites, and enrolling clients as well as regulations for the prescribing, supply and supervised dosing of these medicines.
- While the majority of clients access ODT medicines from community pharmacies, other dosing sites include correctional facilities, clinics and health services.
- Currently, clients are not charged a standard PBS co-payment and no Commonwealth subsidy is provided for dispensing and dose management activities.



## ODTP PMR Progress to date

---

- The ODTP PMR was announced on 24 March 2021.
- The Terms of Reference for the Review were finalised on 30 June 2021.
- A public consultation process was held, where stakeholders could submit their input towards the Terms of Reference for the Review. We received 35 responses which have been published on the ODTP PMR website.
- A Reference Group of experts has been established and is providing advice to the Department throughout the Review process.
- Release of a draft Review Report for consultation is expected by late May.



## PBS listing considerations for ODTF medicines

---

- The *National Health Act 1953* sets out how PBS arrangements operate.
- General schedule medicines (s85) are often supplied to patients on a monthly basis, attract a set PBS co-payment and access is largely limited to dispensing in the community pharmacy setting only.
- Section 100 (s100) of the National Health Act allows for special arrangements to be made if a general schedule listing is inadequate for certain medicines – for example, this could be to support access to medicines from non-pharmacy access points.
- Duplication of medicines across multiple schedules is rare. Where this occurs in the PBS there are usually differences relating to indications for use, formulation, strength of the medicine and maximum quantity that can be prescribed.
- Running two different parallel programs through s85 and s100 has the potential to create a more complex and duplicative program.



## Poll questions

---

- A series of multiple choice poll questions are available in the chat window
- Please work your way through the questions
- The results will update live as your answers are submitted



## Discussion Questions

---

1. What aspects of the current PBS Opioid Dependence Treatment Program (ODTP) work well in your setting?

In that context, what elements of the program do you think should continue in any reformed version of the program?

2. If you haven't introduced or are in the process of introducing opioid dependence treatment (ODT) into your service, what are the barriers?
3. What are the barriers for you, or for others you know, to scale up ODT?
4. What needs to change to overcome the barriers to access?

Additional input regarding the discussion questions can be submitted via email ([ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au))



## Discussion Questions cont. (2)

---

5. **A.** Would barriers to access be addressed if medicines for ODT were PBS listed similar to other PBS medicines?  
**B.** Could there be any unintended consequences if ODT medicines were PBS listed similar to other PBS medicines?
6. In a pharmacy setting, would remuneration for the supply of ODT medicines enable the program to be scaled up so that more people can receive treatment?
7. What else would facilitate scaling up?
8. Please describe how the supply chain for ODT medicines works in your setting i.e. for sponsors /wholesalers/community pharmacy/non-pharmacy dosing sites?

Additional input regarding the discussion questions can be submitted via email ([ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au))



## Discussion Questions cont. (3)

---

9. **A.** How has the introduction of long-acting injectable buprenorphine (LAIB) affected ODT?  
**B.** What is working well in regard to this product in your setting and what can be improved?
10. COVID-19 has highlighted challenges with the provision of ODT services but might also be said to have created some opportunities to innovate how ODT is delivered. What are the lessons learnt during the pandemic and how can they inform future improvements to the ODTP?
11. Is there any other constructive feedback about your experience with ODT medicines that you can provide?

Additional input regarding the discussion questions can be submitted via email ([ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au))



## Question and Answer Session

---

- Please submit your questions via the chat function.
- We may take some of your questions on notice if necessary. Questions on notice will be answered in the Forum summary report when it is published.

Additional input regarding the discussion questions can be submitted via email ([ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au))



## Conclusion

---

- Thank you for attending the ODTP PMR Stakeholder Consultation Forum.
- If you have any further contributions towards the focus questions or would like to add any information regarding the discussions that were had, please submit your input via email to [ODTP.PMR@health.gov.au](mailto:ODTP.PMR@health.gov.au) by 5pm Thursday 3 March 2022.
- Future updates to the Review will be posted on the ODTP PMR website, including a summary of this meeting.
- ODTP PMR website: [www.pbs.gov.au/info/reviews/post-market-review-of-opiate-dependence-treatment-program](http://www.pbs.gov.au/info/reviews/post-market-review-of-opiate-dependence-treatment-program)