

16 December 2022

Post-market Review Secretariat
Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601

Via email: PBSpostmarket@health.gov.au

Dear Post-market Review Secretariat,

Re: Consultation on the revised PBS Post-market Review (PMR) Framework

The Royal Australian College of General Practitioners (RACGP) thanks the Department of Health and Aged Care for the opportunity to comment on the revised PBS Post-market Review (PMR) Framework. We welcome the update to the Framework, particularly the streamlining of processes to help expedite reviews. We provide the following feedback for consideration.

1. Activities preceding a PBS Post-market Review

1.1 Recommendation for a Post-market Review by the PBAC

1.1.1 Prioritisation based on risk

Post-market reviews should be prioritised according to the level of risk, to ensure that resources are allocated appropriately. Consideration of level of risk should include potential:

- patient harms
- economic harms
- reputational harms
- magnitude of harms
- likelihood of harms.

The RACGP recommends the Framework includes explicit criteria for determining the level of risk, according to the harms. The determination of risk would then define the next actions to take. For example:

- **Very low / low risk reviews** – the Framework should outline further actions to be undertaken, including some flexible resolutions (such as cessation of further assessment, immediate recommendations based on internal expertise e.g., PBAC, original rapid review team). A process for appeal should be available if a stakeholder believes that the wrong decision has been made.
- **Moderate / high risk reviews** – similarly, the Framework should outline the level of action and resourcing required depending on the seriousness of the risk.

1.1.2 Review deadlines

Following the risk prioritisation process, we recommend the inclusion of explicit guidance for review deadlines. For example, *'this review should be completed by X months and must be completed by Y months.'* These deadlines should alter depending on whether the review is classified as low, medium or high risk, with review processes coordinated to correspond to these stated deadlines.

2. PBS Post-market Review Process

2.1 Reference Group

It is important that consumer consultation is built-in throughout the review process. This will provide different perspectives on how decisions made during the review would affect health consumers. This includes out-of-pocket costs and how it affects access, which should be an important consideration as part of the review process.

3. Appendix

3.1 Utilisation Analysis

The RACGP welcomes updates to the utilisation analysis. The existing structure suggests that information still comes from the Bettering the Evaluation and Care of Health (BEACH) study, which has been defunded.

3.1.1 Data-informed system

For future reference, the RACGP recommends a robust, data-informed system is developed to improve adverse drug event reporting and to help inform subsequent PMRs. The current system relies on reports being made into a separate system, which can be time-consuming. When a patient is advised by their general practitioner (GP) to stop a particular medicine, some clinical software systems ask for the reason the medication has been ceased. These de-identified records could be automatically reported to the TGA. The TGA could work with general practice organisations and general practice data-extraction providers to provide useful information on:

- demographics of patients using the medicines
- co-prescribed medications including non-PBS medications
- completeness of pathology monitoring of medications
- diagnoses and reasons for visits associated with medicines.

It is important that secondary use of general practice data adheres to the principles laid out by the RACGP ([Guiding principles for managing requests for the secondary use of de-identified general practice data](#)) with a particular emphasis on expert GP involvement in the interpretation of data and implications for practising GPs.

This data analysis should be used in conjunction with evidence reviews and include context from relevant medical professions. In the future, data linkage could then be used across all health sectors, including identifying emergency department visits, hospitalisations, and deaths associated with medicine-use. In this way, high - impact, low frequency adverse events can be identified and quantified.

Thank you again for the opportunity to provide a submission to the draft PBS Post-market Review Framework. If you have any questions regarding our submission, please contact Mr Stephan Groombridge, National Manager, e-Health and Quality Care at stephan.groombridge@racgp.org.au.

Yours sincerely



Dr Nicole Higgins
President