

Summary of changes between the 2015 PMR Framework, the revised PMR Framework consultation draft, and the 2024 PMR Framework

Background

In 2015, the Australian Government introduced Pharmaceutical Benefits Scheme (PBS) Post-market Reviews (PMRs) as a systematic approach to monitoring medicines following PBS listing, to inform decision making relating to ongoing access and subsidy. PMRs provide evidence and options to the Pharmaceutical Benefits Advisory Committee (PBAC) to ensure patient safety, quality use of medicines and the ongoing cost-effective use of PBS-listed medicines.

PMRs originally followed the 2015 PMR Framework developed in consultation with industry in 2014 and announced by the Minister for Health on 18 March 2015.

In 2022, the 2015 PMR Framework was reconsidered in the context of the new [Strategic Agreement](#) between the Commonwealth and Medicines Australia (MA).

Under Clause 7.5 of the Strategic Agreement, the Commonwealth and MA agreed to:

“Work together with other relevant stakeholders to improve the current PMR Framework with the goal of reducing the timeframe from PBAC recommendation of the commencement of a Review, to completion of the Review, to a timeframe of within 12 months, subject always to the Framework not limiting PBAC independence.”

A draft revised PMR Framework was published for [public consultation](#) from 20 October 2022 to 16 December 2022.

The final 2024 PMR Framework was developed by the Department of Health and Aged Care in consultation with MA and considered stakeholder comments received as part of the consultation process. The 2024 PMR Framework was endorsed by the PBAC in December 2023 and approved by the Minister for Health and Aged Care in January 2024.

A summary of the key changes between the 2015 PMR Framework, the revised PMR Framework consultation draft, and the 2024 PMR Framework, along with the rationale for each change is provided in Table 1 below.

Table 1: Summary of key changes between the 2015 PMR Framework, the revised PMR Framework consultation draft, and the 2024 PMR Framework

Change	2015 PMR Framework	Revised PMR Framework - consultation draft	2024 PMR Framework	Rationale for change
Publication of PMR workplan	Not published	Not published	Published on the PBS website following consideration by the PBAC (1-2 times per year)	<p>In response to feedback that there would be benefit in publishing the PMR workplan to provide stakeholders with early notice of topics that could potentially progress to a PMR.</p> <p>The published workplan would include any new PMR topics recommended by the PBAC as well as the status of ongoing projects within the scope of the PMR Framework.</p>
Two-week public consultation on the PBAC-recommended PMR topic	Not included, allows two-week minimum public consultation on draft Terms of Reference (ToRs)	Not included and no public consultation on the draft ToRs	Included	<p>In response to feedback that stakeholders would welcome an earlier opportunity to provide input into PMR topics, a new two-week consultation process has been included in the 2024 PMR Framework following the PBAC's recommendation of a new PMR topic.</p> <p>This consultation process will replace the two-week consultation process on the draft ToRs in the 2015 PMR Framework.</p> <p>Analysis of PMRs undertaken to date has shown that public consultation on the draft ToRs has not made a material difference to the wording of the final ToRs for PMRs.</p>
Public consultation period on the draft PMR report	Two weeks minimum	Two weeks minimum (four weeks if Review Reference Group [RG] not formed)	Four weeks minimum	Based on feedback that the current minimum consultation period on the draft PMR report is too brief for many organisations and consumers.

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Review ToRs standardised	Not standardised	Not standardised, ToRs developed by the Department and approved by the PBAC	ToRs standardised	<p>Most PMRs have included the same ToRs, i.e., ToR 1 (review of clinical guidelines), ToR 2 (utilisation review), ToR 3 (literature review of efficacy and safety) and ToR 4 (cost-effectiveness review, if requested by the PBAC and based on the findings from the previous three ToRs).</p> <p>Standardising the ToRs will negate the need for approval of the ToRs by the full PBAC committee and the need for public consultation on the draft ToRs, thus streamlining and expediting the PMR process.</p>
New standard ToR 5 to understand the patient experience with the medicine(s) of interest from the perspective of consumers, with a particular focus on considerations specific to First Nations Australians	Not included	Not included	Included in addition to public consultations and an optional stakeholder forum	<p>In the 2015 PMR Framework and the consultation draft of the revised Framework, consumer/patient views were sought via public consultations and an optional stakeholder forum. Consumers were also represented in the RG.</p> <p>A new standalone consumer focussed ToR has been included in the 2024 PMR Framework to assist in capturing considerations identified by patients and their families/carers more fully.</p>
Approval of the ToRs	Approved by the PBAC and the Minister	Approved by the PBAC only	Approved by the PBAC Executive in most cases	Under the 2024 PMR Framework, the PBAC Executive will be requested to approve the final Review ToRs rather than the full Committee. This will expedite PMR timeframes as there can be delays in inclusion on the

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				<p>agenda of a triannual PBAC or PBAC Intracycle meeting.</p> <p>Where there may be the need for a significant deviation from the standard ToRs, the full PBAC committee will be asked to consider and approve the ToRs.</p>
Review Reference Group (RG)	Established for each PMR and involved in the development of the draft report	Optional RG that is only formed if requested by the PBAC and convened after the report has been drafted	Optional RG that is only formed if requested by the PBAC/PBAC Executive	<p>The RG appointment process is lengthy, and it is difficult to schedule RG meetings to accommodate the availability of all appointed members. Clinical experts and peak body representatives have many competing demands on their time.</p> <p>To expedite and streamline the PMR process, a RG will only be established when deemed necessary by the PBAC. For example, when the PBAC considers there is insufficient clinical expertise within its membership and that of its sub-committees to provide advice on the specific research and stakeholder input relevant to the Review.</p>
Commencement of PMR	At the time of the PBAC recommendation for a PMR	Upon approval of the Review ToRs by the PBAC	When the PMR is announced on the PBS website, post PBAC/PBAC Executive approval of the Review ToRs	The 2024 PMR Framework aims for most PMRs to be completed within a timeframe of 12 months from online announcement of the PMR to PBAC consideration of the draft report, consistent with the intent of the Strategic Agreement. More complex PMRs may still extend beyond a timeframe of 12 months.

Abbreviations: PBAC = Pharmaceutical Benefits Advisory Committee; PBS = Pharmaceutical Benefits Scheme; PMR = Post-market Review; RG = Reference Group; ToRs = Terms of Reference.