Post-Market Review Framework

Medicines Australia response to public consultation process

The post-market review (PMR) framework is being reviewed as part of the 2022–2027 Strategic Agreement between the Commonwealth and Medicines Australia (MA). Under section 7.5 of the new Strategic Agreement, the Commonwealth and Medicines Australia agreed to:

> *"Work together with other relevant stakeholders to improve the current PMR framework with the goal of reducing the timeframe from Pharmaceutical Benefits Advisory Committee (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."*

The key aim of the PMR framework review, therefore, is to reduce the time taken for PMRs to a timeframe within 12 months. Medicines Australia welcomes the commitment to create a more efficient process for PMRs that delivers more timely outcomes.

When reviewing the proposed amendments to the PMR framework, Medicines Australia has identified key changes that may go beyond reducing the timeframe for PMRs, instead potentially altering the PMR process in significant ways that are unrelated to the time taken for the review. These proposed changes require further discussion and clarification to ensure that they do not result in negative consequences for patients and other stakeholders.

Medicines Australia is gratified that the Department has committed to ongoing consultation and collaboration on this topic with both Medicines Australia and other stakeholders as the revision to the PMR framework progresses through 2023, to ensure that the revised framework meets the aim of section 7.5 of the Agreement in ways that best serve all key stakeholders.

Comments relating to the proposed framework

1. ***The review of the PMR framework should not result in alterations to the PMR process beyond the scope of the Strategic Agreement***

As discussed in the introduction to this document, the intent of section 7.5 of the Strategic Agreement was to reduce the timeframe for PMRs to within 12 months. However, some aspects of the proposed revisions go beyond this intent.

For example, the revised framework implies a stronger intent to follow through on recommendations made by the PBAC that do not relate directly to the PBS. It includes new provisions for recommendations for future research to be referred to the area of the Department responsible for administering the Medical Research Future Fund (MRFF) for consideration in future grant rounds. Should this be adopted into a revised framework, more information should be provided regarding the opportunity for sponsors to provide input into or feedback on proposed future research. Medicines Australia is willing to work with the Department on the intent of PMRs with relation to the MRFF.

2. ***A more rapid PMR process should have at its core patients' best interests***

The revised draft framework refocuses the intent of PMRs in three key ways:

- A more explicit and detailed focus on improving sustainability of the PBS.

- A new reference to the role of PMRs in informing disinvestment decisions, which is not included in the current framework: 'Evidence from PMRs will guide the continued access, investment or disinvestment in PBS-listed medicines.'
- A newly elucidated prioritisation step, whereby 'The committee will prioritise PMR topics and make a recommendation on the PMRs to be progressed based on a range of factors including, but not limited to … potential impact to the health budget.'

PMRs may play a role in supporting sustainability via informing understanding of actual utilisation patterns and how these compare with the approved conditions of reimbursement and the principles of quality use of medicines. However, while Medicines Australia recognises the impact of PMRs on patients, prescribers and the PBS budget, it is not appropriate for sustainability to be the focus underpinning the PMR process – this may result in the process being applied in ways that do not serve the best interests of patients.

Firstly, the prioritisation framework does not provide sufficient transparency on how topics with implications for the health budget will be prioritised compared with matters related to the quality use of medicines or medicine safety. Prioritising those topics that have the potential to reduce the health budget over other topics is clearly not in the best interests of patients, when safety and quality use of medicines should be the focus of any PMR.

Secondly, the inclusion of an explicit statement that the outcome of PMRs may be used to inform disinvestment decisions could have significant implications for patient access to medicines. MA believes that disinvestment decisions should form a minority of PMR outcomes given the impact on current patient treatment. Any proposed disinvestment decisions could not be supported unless there are significant clinical concerns for patients that need to be addressed. Consultation and transparency in the process of selecting topics for future PMRs and the rationale for these decisions is therefore crucial, to ensure that the process is applied fairly, equitably and appropriately.

While we acknowledge the Department's comments that the proposed changes simply provide more detail on a process that is already happening and that disinvestment decisions go beyond delisting of medicines, the inclusion of these statements without further context or explanation has the potential to result in PMRs being used in ways that are not intended and that are beyond the scope of the Agreement. Taken at face value, the proposed document could be seen to represent a significant shift in the scope and intent of PMRs, with little clarity on the approach to their conduct at a technical level.

3. A more rapid PMR process should retain due diligence

To reduce the time taken for PMRs, the framework proposed by the Department truncates some parts of the process in ways that will be detrimental to informed decision-making.

Firstly, it is important that the process of considering potential PMR topics is not rushed. To inform the PBAC properly and meaningfully with regards to any proposed PMR, processes such as reviewing and evaluating the literature and guidelines, seeking input from sub-committees and expert advisory groups, and sufficient engagement with sponsors and other stakeholders should allow adequate time. It is not clear in the proposed process where or whether these activities will take place prior to the Department deciding which topics to refer to the PBAC for consideration.

Secondly, in addition to the matters previously considered within the remit of PMRs, the revised framework appears to include a cost-effectiveness analysis in parallel to other factors considered during

the PMR, including utilisation. In the current framework, the process typically begins with a utilisation analysis; cost-effectiveness is reviewed later once it has been established that there is an issue that needs to be investigated. Conducting utilisation and cost-effectiveness analyses in parallel is particularly problematic because, under the proposed framework, sponsor companies do not appear to have any visibility of or ability to provide feedback during PMR topic selection.

The current process includes the provision of a DUSC report following PMR topic identification that sponsors have the opportunity to review and comment on, which is not included in the revised framework; however, unless any analysis of utilisation patterns is undertaken as part of the PMR topic identification process, it is unclear how grounds for a cost-effectiveness review can be supported but rather requires making *a priori* assumptions regarding utilisation patterns beyond what was agreed as part of the initial assessment of a medicine and the implications for cost-effectiveness.

Further detail is required about the way in which PMRs will be conducted under the proposed framework. Cost-effectiveness should not be considered as a topic for a PMR without the requirement to first establish patterns of utilisation which are inconsistent with the approved conditions of reimbursement, which the PBAC has accepted as cost-effective, including where the clinical evidence has not changed.

MA remains concerned about the language used in the proposed changes to the PMR processes that appear to prioritise concepts such as sustainability, cost-effectiveness, conditional listings and disinvestment ahead of improving quality use of medicines and access to PBS medicines

PMRs are resource-intensive and play a significant role in informing important decisions related to investment, disinvestment, and patient access. Therefore, the revised process should be grounded in the principles of the scientific method of hypothesis development and testing. They should begin from the standpoint of seeking to understand, rather than making a priori assumptions upfront that could result in a flawed process and recommendations that are not evidence-based.

It is important that any revised process allow sufficient time for robust review and appropriate timing of associated analyses to ensure that the process does not pre-empt outcomes.

4. A more rapid PMR process should retain sponsor and stakeholder consultation

To meet the goal of reducing the timeframe for PMRs to 12 months, the draft revised framework proposes to remove a number of opportunities provided under the current framework for consultation with affected sponsors and other relevant stakeholders, and reduces the ability to provide meaningful and detailed feedback on key elements of the process.

Medicines Australia has significant concerns about the lack of sponsor and stakeholder consultation built into the revised process. It is our contention that the revised process should retain at least 6 weeks of consultation throughout the process, to ensure that the stakeholder voice is heard and that the process remains accurate, collaborative and transparent.

Specifically, we have concerns about the following proposed changes to the framework.

Consultation during PMR topic identification

There is no visibility on or ability to provide feedback during consideration of possible topics for future PMRs, or the opportunity to review analyses which inform the decision to pursue a PMR. The current

framework provides for consultation with sponsors via provision of a DUSC report, with the opportunity for sponsors to comment, prior to the PBAC making a recommendation to the Minister that a PMR be undertaken.

We note the Department's comments that all relevant documentation will still be provided to sponsors, but the timing of provision of these documents and the opportunity for sponsors to provide comments on them is unclear; if it is still the Department's intention that the process outlined in Figure 2 of the current PMR framework remains as part of the revised framework, this should be made clear.

Consultation on the draft terms of reference

As identified in the public consultation survey, the proposed process will no longer include public consultation on the terms of reference (TORs) for PMRs. Removing this step may result in TORs and research questions that do not appropriately address important considerations of relevant sponsors, healthcare professionals and patients in relation to the PMR, or potential gaps in the evidence development plan. The current process provides for a 2-week consultation period on the TORs. It is Medicines Australia's contention that the public consultation on the draft TORs must remain as part of the process.

Inclusion and timing of Reference Groups and stakeholder forums

A PMR reference group and stakeholder forum are now optional as opposed to standard parts of the process, and the determination regarding the need for a reference group or stakeholder forum rests with the PBAC.

Medicines Australia believes that a Reference Group is a crucial step in any PMR. Based on feedback from sponsor companies, a Reference Group provides important clinical and patient perspectives on the treatment(s) undergoing a PMR. These perspectives are based on practical experience and provide the PBAC with important clinical context.

The scope of the Reference Group is limited under the revised framework to '…provide independent, expert advice on the draft Report prior to consideration by the PBAC', and it appears that these groups will only be convened after a report is produced. This is very late in the process and misses the opportunity for expert input into the TORs and research questions which would better inform the development of the draft report, as well as the content of the report itself.

The revised framework states that stakeholders may also request that a stakeholder forum be held during consultation on the TORs but, because this consultation on the TORs will no longer take place under the proposed framework, it is not clear when stakeholders would have the opportunity to raise the need for a stakeholder forum.

If a stakeholder forum is held, under the revised process it will take place after the public submission process and via webinar rather than face-to-face. The order and timing of these processes may require further consideration to ensure that the discussion and rich insights that come out of a stakeholder forum take place at the optimal time to inform the PMR.

Finally, under the proposed framework, the call for public submissions addressing the PMR will take place after the TORs and research questions are finalised; public consultation will occur in parallel with the evidence development process undertaken by the Department, which could include conducting literature searches, utilisation analyses and economic analyses. There is insufficient detail in the revised

framework on how these two processes interact, with the risk that the draft report does not sufficiently address and incorporate the totality of the evidence relevant to the PMR.

5. A more rapid PMR process should retain transparency

The revised framework does not appear to commit to the same level of transparency as the current framework and puts more onus on stakeholders to proactively keep abreast of PMRs. There are several areas where transparency in the proposed process is less than under the current framework. As a minimum, the transparency in the existing process should be maintained in any revised framework.

- While the draft framework more clearly elucidates which stakeholder groups may trigger a PMR, it is not explicit in outlining what may trigger a review. Under the current framework, the triggers are clearer. Under a revised framework, the criteria for initiating a PMR should be outlined and the rationale must be transparent. DUSC reviews should remain a trigger and should enable increases as well as decreases in conditions, restrictions and price.
- The current framework includes a commitment to publish information related to PBAC meeting dates, agendas, outcomes, and details regarding current and completed PMRs on the PBS website. This appears to have been removed from the revised framework.
- There is no indication in the proposed framework that topics for consideration referred to the PBAC by the Department will be publicised on the PBAC agenda.
- Wording related to the notification of sponsors and other key stakeholders if a PMR report will be considered at an out of session PBAC meeting appears to have been removed from the draft framework.
- The commitment to provide information regarding the implementation and progress of recommendations for each PMR via updates on the PBS website as it becomes available appears to have been removed.
- Provisions for sponsors to request a full copy of any analyses conducted during the PMR, including any economic and drug utilisation analysis, appears to have been removed.
- The revised framework links timing of provision of the minutes relating to the PBAC's consideration of the PMR draft report to the timing of the publication of the PBAC outcomes (6 weeks post-meeting) which was not included previously; however, it is not clear how far in advance of the outcomes being published the minutes will be provided, nor does there appear to be any opportunity for sponsors to provide feedback on the minutes/correct any errors of fact or provide feedback on the wording of the PBAC outcome published for the PMR.

Ensuring transparency of the process should be a key pillar of any revised framework. If it is the intention of the Department that these processes remain as part of a revised framework, this should be made explicit in the PMR framework document to avoid them being overlooked.

6. A more rapid PMR process should retain appropriate 'checks and balances'

Under the revised framework, key activities that previously involved input from other individuals or groups have been delegated to the Department or the PBAC.

- The Department will compile proposed topics for PMRs with no apparent opportunity for sponsors to provide feedback, or to review any documents or analyses used to inform recommendations related to PMR topics or prioritisation.
- The role of the DUSC in the process is unclear, and there is no indication that a utilisation analysis will be conducted prior to commencement of a review to determine whether an issue exists that requires a PMR.

- The PBAC will make a decision on the final TORs for the PMR without any requirement to consult with impacted stakeholders or the public, and the Minister for Health is no longer required to approve the TORs but rather is informed once the PBAC has written them.
- The PBAC will determine whether a stakeholder forum or reference group is required. Sponsors can only request a stakeholder forum very late in the process after the topics have been selected and prioritised, the TORs have been finalised and the draft report has been prepared, which calls into question the ability of the stakeholder forum to meaningfully provide input into the PMR process.

The removal of some of these 'checks and balances' in the PMR process, coupled with apparent reductions in transparency, consultation and input from stakeholder groups (patients, healthcare professionals, and the pharmaceutical industry) introduces the potential for the process to result in negative consequences for patients and others through lack of balanced information.

Interaction with other policies and processes

Other sections of the Strategic Agreement

It is not clear how the proposed PMR framework may interact with other sections of the Strategic Agreement, such as the HTA review that has recently been launched. Consideration of the way in which the PMR framework may impact or be impacted by any policy changes that arise from the HTA review or other elements of the Agreement would be beneficial.

National Medicines Policy

Although the revised process refers to the National Medicines Policy, no detail is provided on how the priorities established via the NMP will inform PMR topic selection and prioritisation.

Horizon scanning

Although the horizon scanning process is still under development, the revised framework does not pre-empt its introduction or discuss in any way how the two processes may interact.

Conditional listings

While the scope and processes relating to the introduction of conditional listings are still to be determined, the revised framework potentially foreshadows an interaction with conditional listings by highlighting the role of PMRs in informing disinvestment decisions. Further detail is required on how these processes will interact.

Risk-sharing arrangements (RSAs)

The provision under the revised framework to consider cost-effectiveness upfront is problematic in the absence of a pre-emptory review of utilisation patterns. The revised PMR framework does not discuss RSAs. Given that RSAs are routinely used by the PBAC to address the potential for use outside the eligible cohort in a population, which may be less cost-effective but can also address patterns of utilisation within the eligible cohort which may not be cost-effective, PMRs targeted towards reviewing cost-effectiveness should not be conducted for therapies where there are already existing mechanisms in place to address concerns related to cost-effectiveness, or could be used to assess the need for ongoing RSAs.

Interactions with other government departments and agencies

While the revised framework discusses the role of PMRs in investigating topics related to safety, QUM or service provision gaps, there is no discussion of how the process will be managed in a coordinated way with other relevant stakeholders such as the TGA, the Australian Commission on Safety and Quality in Healthcare or the MSAC/MBS.

Parallel frameworks

Other frameworks that run in parallel to PMRs must be respected during any PMR. Medicines Australia considers the following to be additional pricing measures that should be outside the scope of PMRs:

- Reviewing one product and having any changes made extend to other products
- F1/F2 price separation
- Statutory price cut impacts impacting the base prices of medicines within the scope of a PMR and using an outcome to flow on to other medicines
- Reference pricing when loss of exclusivity, statutory price reductions or F1/F2 price reductions have been involved.

Medicines Australia looks forward to working with the Department in helping to shape the revised PMR framework in a substantive way through direct consultation in 2023.