13 February 2025

PBS Improvements Section
Department of Health and Aged Care
pbscostrecovery@health.gov.au

Re: Draft Cost-Recovery Implementation Statement: Submission from Medicines Australia

Medicines Australia appreciates the opportunity to participate in the public consultation on the *Draft Cost Recovery Implementation Statement (CRIS) for Listing Medicines on the PBS and Designated Vaccines on the NIP 1 July 2025 – 30 June 2026*.

Key requests

In response to the draft CRIS for 2025–26, Medicines Australia asks the following.

- Early and broad consultation on the impact of the time-and-motion study on cost recovery fee changes well in advance of the development of the draft CRIS for 2026–2027.
- More details on the likely impact on future fee changes of the reclassification of the Health Products Portal (HPP) as a service rather than an asset.
- An early bilateral meeting between the DoHAC and Medicines Australia to collectively design and contribute to cost recovery items sooner in the process, noting the Department's need to fit within Budget processes.
- Agreement on a formula for the calculation of baseline fee changes, and a commitment to consult on fee increases higher than those generated using the agreed formula.
- Removal of, or full exemption from, cost recovery fees for orphan-designated medicines.
- Consideration of alternative fee structures for specific types of medicines including vaccines and orphan medicines to help facilitate reimbursement of these critical therapies.
- Commitment from the Department of Health and Aged Care (DoHAC) to ongoing consultation on any activities that may be considered for cost-recovery purposes, including reforms recommended as part of the HTA Policies and Methods review.

Each of these is discussed in more detail below. Comments on additional aspects of the draft CRIS are also provided towards the end of this submission.

Time-and-motion study

In paragraph 6.9.2 of the Strategic Agreement, there is a commitment '*to undertake a review during 2022 of the PBS activity-based cost model to assess the appropriateness of the list of cost recovered activities in the administration of the PBS and the cost allocations to them having regard to the Australian Government Charging Framework and Australian Government Cost Recovery Guidelines'*. This review is complete, but key recommendations of the resulting report have yet to be addressed in full.

The 2022 Independent Review of the PBAC Activity-Based Cost Model made four key recommendations including the time-and-motion study, which has been ongoing for some years but for which the results have not been presented. The 2023–24 CRIS stated that *any 'efficiencies found will be reflected in amended fees charged in the 2024–25 financial year'*. The 2024–2025 CRIS stated that '*outcomes of the review would be reflected in fees for the 2025–26 financial year'*. The 2025–2026 CRIS states that '*outcomes of the ongoing review will be reflected in fees as they become available'.*

We note that the time-and-motion study is likely to impact next year's CRIS. We request that, when the results of the time-and-motion study are completed and the impact of the study on the cost recovery fees have been determined, the Department meet with Medicines Australia well in advance of the

2026–27 CRIS consultation to discuss any proposed fee changes. This will allow our membership to conduct early forward planning, creating greater business certainty.

Reclassification of the Health Products Portal as a service

The draft CRIS for 2025–2026 includes reductions in some capital costs and increases in some direct costs compared with the previous CRIS, presumably related to this change in categorisation, and highlights that the fees relating to the HPP are significant for certain submissions categories (for example, Category 1 submissions are priced at about $16,000 based on the change in direct costs from last year to this year).

It is not yet clear what impact (if any) this reclassification will have on cost recovery fees for the 2026–2027 CRIS. We would like more context around the statement that "the HPP has been reclassified to a Software as a Service (SAAS) arrangement *and costs will be expensed when they are incurred*" [emphasis added]. We seek clarification of the implications of this statement, and the reclassification of the HPP more generally, on future cost recovery fees. Should the reclassification from an asset to a service lead to the proposed introduction of new fees, we ask for early and broad discussion, engagement and consultation significantly in advance of their implementation.

Bilateral meeting between the DoHAC and Medicines Australia

As the peak body representing the innovative, research-based medicines industry in Australia, we seek to engage early in the cost-recovery process to collaboratively design and contribute to the changes to cost recovery fees, and to enable medicines sponsors to more accurately forecast for business planning purposes. We acknowledge that the 2025–2026 CRIS consultation is occurring significantly earlier than in previous years, which goes some way to allowing our members and other stakeholders to plan and forecast in a timelier way. However, there are other measures associated with the CRIS consultation that could further assist with business planning.

Medicines Australia seeks an early bilateral meeting with the DoHAC to collectively design and contribute to cost recovery items sooner in the process, noting the Department's need to fit within Budget processes. While the Therapeutic Goods Administration (TGA) holds regular bilateral meetings with Medicines Australia early in the process to discuss and consult on cost recovery fees for registration of medicines, to date no similar early bilateral consultation has occurred for fees relating to reimbursement of those same medicines. Such an arrangement would assist medicines sponsors by allowing appropriate time for business planning.

It remains critical that public consultation is undertaken with all stakeholders before the implementation of any fee changes.

Agreement on baseline fee changes

The TGA and Medicines Australia have agreed a formula for the calculation of baseline registration-related fee changes, but an equivalent formula has not been agreed for reimbursement-related fees. This has led to significant and highly variable fee increases historically, which makes forecasting unpredictable, business planning difficult and contributes to the reimbursement environment in Australia being unattractive to international medicines companies.

We note that the proposed fee increases for the next financial year are generally in line with or below CPI. However, given the magnitude of and variability in fee increases in previous years, fees remain high and continue to pose a possible barrier to entry for some medicines, as discussed in more detail below. Agreement to a formula for calculating baseline fee changes, coupled with early consultation on any fee changes that deviate from this formula, could help to mitigate some of the uncertainty around cost recovery year-on-year.

Removal of, or full exemption from, cost recovery fees for orphan-designated medicines

Medicines designated as orphan medicines by the TGA are exempted from cost-recovery fees for the first PBAC submission. Medicines Australia remains concerned about the significant fees applicable to orphan medicines and we seek a return to fee exemption for all cost recovery elements, not just the first submission, for these medicines. A worked example of the significant fees associated with gaining reimbursement for an orphan medicine is provided below under 'Total cost to reimburse medicines' (example B).

Given the level of evidence generally available for orphan populations, submissions for orphan drugs are frequently associated with a higher degree of uncertainty: if the evidence base is limited and raises clinical uncertainties, the economic analysis is also considered uncertain. This means that a first-time positive recommendation from the PBAC is less likely for orphan medicines than for those affecting larger populations with a more robust evidence base, so achieving a positive recommendation often resubmissions to address the uncertainty. This is associated with a significant cost and may have a negative impact on the financial viability of the medicine in question, resulting in medicines intended to treat conditions with the highest unmet need being delayed or not brought to market. Exemptions from all reimbursement-related fees would help mitigate this risk.

Consideration of alternative fee structures for certain therapies

Medicines Australia members continue to raise concerns about the equitable application of the cost recovery fees, and the difficulty for applicants to list or seek waivers or exemptions for lower-revenue products that address an unmet clinical need. Given the cumulative size of the fees to seek listing on the ARTG and the PBS, Medicines Australia seeks consideration of alternative fee structures, ensuring medicines and vaccines remain viable prospects for PBAC consideration and are ultimately made available to patients.

Medicines Australia seeks a consultation on alternative solutions, including:

- A risk-share approach to the fees for medicines and vaccines that have a projected revenue of less than $5–10 million per year. For these products, 50% of the fees could be charged up front, whilst the remaining 50% could be charged once the medicine or vaccine reaches its projected revenue, or waived entirely.
- A phased payment based on the size of the company or a fee structure reflective of the expected revenue for an individual product.

The application of equitable fees is not a new concept and has been applied by HTA agencies such as NICE in the United Kingdom. NICE separates costs based on company size (large versus small) and for small companies, fees are significantly less.

Medicines Australia notes that these suggestions were provided as part of the CRIS consultations for the past three years. Medicines Australia would welcome the opportunity to discuss these alternative solutions in more detail.

Commitment to consultation on any newly cost-recovered activities

In late 2024, the report from the Health Technology Assessment [HTA] Policy and Methods Review was released, containing 50 recommendations for reforms to the existing HTA system. We seek a commitment from the DoHAC to ongoing consultation on any activities that may be considered for cost-recovery purposes generally, including reforms undertaken as part of the HTA Review. As discussed previously, early and broad stakeholder engagement and consultation is critical to ensuring a viable system.

Further comments

We offer the following additional comments about the draft CRIS for 2025–2026.

Specific fee increases

Medicines Australia notes that highest fee increases are in the order of 3% compared with the fees in the 2024–25 CRIS, these being for ATAGI pre-submission evaluations for both simple and complex submissions. We request more detail about how these fee increases were derived and why vaccine-related fee increases are higher than others, particularly given the ongoing complexity of the process for review and listing of vaccines on the NIP and delays to the listing of some vaccines relating to ongoing lengthy reviews by the ATAGI (such as the pneumococcal review currently being undertaken, which began in mid-2023 and has no visible end date).

We also note the proposed 1.5% increase in the fees for Ministerial determinations for stockholding requests, following a 6.3% increase in this fee in the 2024–2025 CRIS. Medicines Australia acknowledges the work being undertaken by the DoHAC to streamline the reporting process for stockholding shortages and outages. We look forward to ongoing review of the impact of the stockholding requirements on medicines shortages to contextualise these fee increases, including whether the portal being developed to help facilitate reporting will be factored into fees in future.

Predicted volume of submissions

We note that the predicted volume of submissions for the 2025–2026 financial year (Table 8, draft CRIS 2025–2026) has remained flat from the previous year (Table 8, CRIS 2024–2025). This is questionable, especially given the fluctuations in the number of submissions per PBAC meeting observed over the past year. We would welcome further information about the implications of this flat submission volume forecast on fees and Departmental resourcing.

Total cost to reimburse medicines

Based on an analysis of the likely activities required for an innovative medicine to navigate the process to achieve PBS listing, an applicant is likely to incur costs, on average, in excess of $600,000. This does not include the significant costs related to evidence generation, TGA cost recovery fees and submission preparation. Based on the fees, it is important to consider that cost recovery may be a significant barrier for entry in Australia for some innovative medicines.

Three examples of the cost estimates to achieve PBS listings are:

- **Example A: Innovative medicine – the proposed 2025–2026 fees would require a total investment in cost recovery fees of around $645,440, an increase of $12,600 (1.95%) compared with the 2024–2025 CRIS.**
  - Based on 1 x pre-submission meeting, 1 x Category 1 submission, 1 x Standard Re-entry submission and 1 x Pricing pathway A submission.
- **Example B: Orphan drug – the proposed 2025–2026 fees would require a total investment in cost recovery fees of around $375,590, an increase of $4,490 (1.2%) compared with the 2024–2025 CRIS.**
  - Based on 1 x pre-submission meeting, 1 x Category 1 submission, 1 x Standard Re-entry submission and 1 x Pricing pathway A submission.
- **Example C: Vaccine – the proposed 2025–2026 fees would require a total investment in cost-recovery fees of around $807,000, an increase of $almost $18,000 compared with the 2024 – 2025 CRIS.**
  - Based on 1 x ATAGI Complex Submission, 1 x Category 2 submission, 1 x Standard Re-entry submission and 1 x Pricing pathway A submission.

As in previous years, the commencement date for any fee increases should allow for reasonable business planning.

Removal of levy-related activity

As in the previous CRIS, the draft 2025–2026 CRIS acknowledges that in 2018–19 the former Government decided not to apply a PBS listing levy and the relevant activities continue to be funded by the Government via an appropriation to the DoHAC.

However, also as in the previous CRIS, the 2025–2026 draft CRIS states that "*This partial cost recovery approach will continue to be reviewed as required under the Australian Government Charging Framework".* The statement remains a concern for the industry, because this is not a long-term solution and should not be considered in isolation.

Medicines Australia again requests that the above italicised statement be removed from the CRIS and that this position be revised. Any future consideration of changes to the structure of cost recovery fees will be subject to consultation with the industry.

Medicines Australia remains committed to working with the DoHAC to deliver equitable, transparent and fit-for-purpose process improvements to the listing of medicines on the PBS and ensuring timely and affordable access to new medicines for all Australians. In the spirit of open and constructive consultation, we look forward to an ongoing dialogue about cost recovery for the activities occurring to establish and maintain access to medicines and vaccines for Australians.

Yours sincerely,

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Medicines Australia