Fact Sheet: Proportionate appraisal and early resolution

Medicines Australia

The HTA Review recommends that health funding and assessment processes be fit-for-purpose and proportionate to the level of risk, complexity and potential benefit of a therapy.

The HTA Review finds there is currently limited differentiation between low risk, simple submissions and high-risk complex submissions. The current system does not differentiate between the level of time and effort required for developing and evaluating a submission. The Review makes recommendations to prioritise time and effort where it is most needed and useful for clinical outcomes to speed up patient access to new medicines.

Relevant and positive recommendations are:

- Triaging submissions to determine the appropriate evaluation and appraisal mechanisms (Recommendation 5).
- A streamlined pathway for cost-minimisation submissions (Recommendation 7).
- An enhanced early resolution pathway for more complex submissions (Recommendation 8), providing greater flexibility for resubmission, a case manager and the ability for the PBAC to hold stakeholder meetings. This would be extended to all therapies claiming clinical benefit over existing alternatives after a trial period and review (Recommendation 9).
- Decoupling of the TGA delegate overview from PBAC advice to enable full parallel processing (Recommendation 8).
- A proportionate appraisal pathway for vaccines with a single front door mechanism for sponsors of a vaccine to make a submission to the National Immunisation Program to the TGA, ATAGI and PBAC (Recommendation 11).

Medicines Australia did make a comment in the Report on the need to ensure no perverse incentives are introduced into this pathway and to note that industry recommends establishment of an independent dispute resolution and commercial negotiation process.

Key takeaways

- These improved pathways for PBS listing will reduce the time and effort spent on low-risk, simple submissions and ensure that funding and assessment is proportional to the complexity, risk and potential benefit of a therapy.
- Time to access for patients will be reduced, with the Report noting that the timeframe for patients to have subsidised access to HATV therapies would be around 16 months faster.