

# Fact Sheet: Bridging Fund



The HTA Review recommends a Bridging Fund be established to facilitate faster patient access to new medicines outside the PBS.

Industry advocated for a Bridging Fund for provisional access. The concept of a Bridging Fund is supported by stakeholders and will facilitate faster access to medicines where there is unmet need.

The Review recommends the establishment of a Bridging Fund (Recommendation 20) to facilitate earlier, temporary subsidised access for promising, time-critical, therapies of high added therapeutic value that address high unmet clinical need.

While there are still many details that need to be determined, the recommendation states the Fund should not introduce unnecessary complexity into the system, nor create unintended consequences that would prolong assessment, negotiations, or implementation of agreed terms and conditions between stakeholders.

It also determines the Fund should:

- Be a dedicated but separate budgetary allocation, distinct from baseline Commonwealth healthcare funding arrangements.
- Be designed drawing on international experience including that of the UK.
- Feature specific eligibility requirements including:
  - Process-related qualifying requirements, such as earlier submission of health technologies for evaluation via the TGA/ HTA parallel submission process within a defined period after first major international regulatory approval (e.g. no later than 6-9 months after FDA/EMA marketing authorisation; or within a defined period after identification as part of the high unmet clinical need identification process.
  - Specific situational circumstances that a qualifying health technology needs to meet arising from the HTA evaluation process.
- Have eligibility requirements including agreement to post-HTA recommendation milestones and conditions, agreement on the costs and duration of bridging funding to ensure that the available appropriation allocations are not exceeded, and clear transition pathways and processes (including stakeholder communications).
- Develop appropriate governance arrangements for the Bridging Fund, including a scheduled evaluation to examine whether the Fund is addressing key objectives.
- The Fund will need clear criteria for entry and exit and 'high unmet clinical need' must be defined. It should also be agnostic to both therapy area and technology. The relationship with Managed Entry Arrangements (a separate revised policy at Recommendation 19) will need to be articulated.

The Bridging Fund will provide a pathway to accelerate access to new medicines. Medicines Australia will work with members and other stakeholders to co-design a Bridging Fund.