



Medicines
Australia

Better health
through research
and innovation



Strategic Agreement 2022-2027

Building a Future for Earlier Access to New Medicines

Medicines Australia has secured a 5-year Strategic Agreement with the Federal Government, centered on earlier patient involvement and influence in the availability of new medicines in Australia.

The new Agreement sets out a hardworking, five-year plan that heralds a new era by securing stronger patient involvement in critical processes and ensuring Australia keeps pace with rapidly transforming medical advancements developed around the world.

What is a Strategic Agreement?

A strategic agreement is the establishment of a mutually beneficial relationship between two organisations to pursue a set of shared goals.

The shared objectives for the Medicines Australia and Government Strategic Agreement are:

- Forging an innovative future for patients to access cutting edge medicines
- Driving greater patient involvement in assessing and listing new medicines
- Delivering better outcomes for patients.

What are the benefits for patients?

1. INDEPENDENT HTA REVIEW

- In a major step forward, patients will become fundamental contributors to the first independent review of Australia's Health Technology Assessment (HTA) system in nearly 30 years. Our HTA system reviews new medicines and technologies to recommended which ones should be funded available in Australia.
- A patient representative will be appointed to the HTA Review Committee. This will ensure medicine recommendations are informed by patient perspectives and experiences.

To find out what the HTA is click here.

2. ENHANCED CONSUMER ENGAGEMENT WITH THE PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC)

- A new Enhanced Consumer Engagement process will be developed which will incorporate consumer and patient perspectives earlier in the PBAC process when assessing a new medicine for listing on the Pharmaceutical Benefits Scheme (PBS). The ability to have earlier involvement in this process will allow consumer and patients to highlight the value of new medicines to them beyond the monetary cost. This new process will be co-designed with consumers, patients, clinicians, the medicines industry, and other health professionals in the first year of the agreement.
- The new Enhanced Consumer Engagement process will reflect the issues arising from new technologies and medicine innovations, particularly those patients with high unmet needs. It will consider **patient-defined** needs at the start of the PBAC process, rather than towards the end, which will drive further efficiencies in access to medicines.

To find out more about the PBAC, click here.

To find out more about the PBS, click here.

3. EARLIER ACCESS THROUGH CONDITIONAL LISTINGS

- Currently under the Therapeutic Goods Administration (TGA), certain promising new medicines are fast tracked, where the TGA assess that the benefit of early availability of the medicine outweighs the risk of waiting while additional data is collected. This is referred to as a "provisional registration". This means that some prescription medicines that provide a major therapeutic advancement for Australians could come to the market up to two years sooner than in the current framework.

- Under the new Strategic Agreement, revised **conditional listing and funding arrangements** will deliver new medicines to patients even earlier and faster, building on the TGA's fast-track registration processes. The Government and Medicines Australia will work together on the arrangements starting in July 2022.

To find out more about the TGA click here.

4. MEDICINE SUPPLY CHAINS

- Implementation of new measures, such as 4-6 month minimum stockholding requirements in certain circumstances, will help to reduce medicines shortages.

5. FUNDING THE PBS

- Working together, the Australian Government commitment in 2020 to the New Medicines Funding Guarantee which provides at least \$2.8 billion dollars over the first four years, and savings of approximately \$1.9 billion from the New Strategic Agreement, will be fully re-invested in the PBS, ensuring at least \$5 billion of uncapped new investment is available for Australians to have the earliest possible access to innovative medicines.

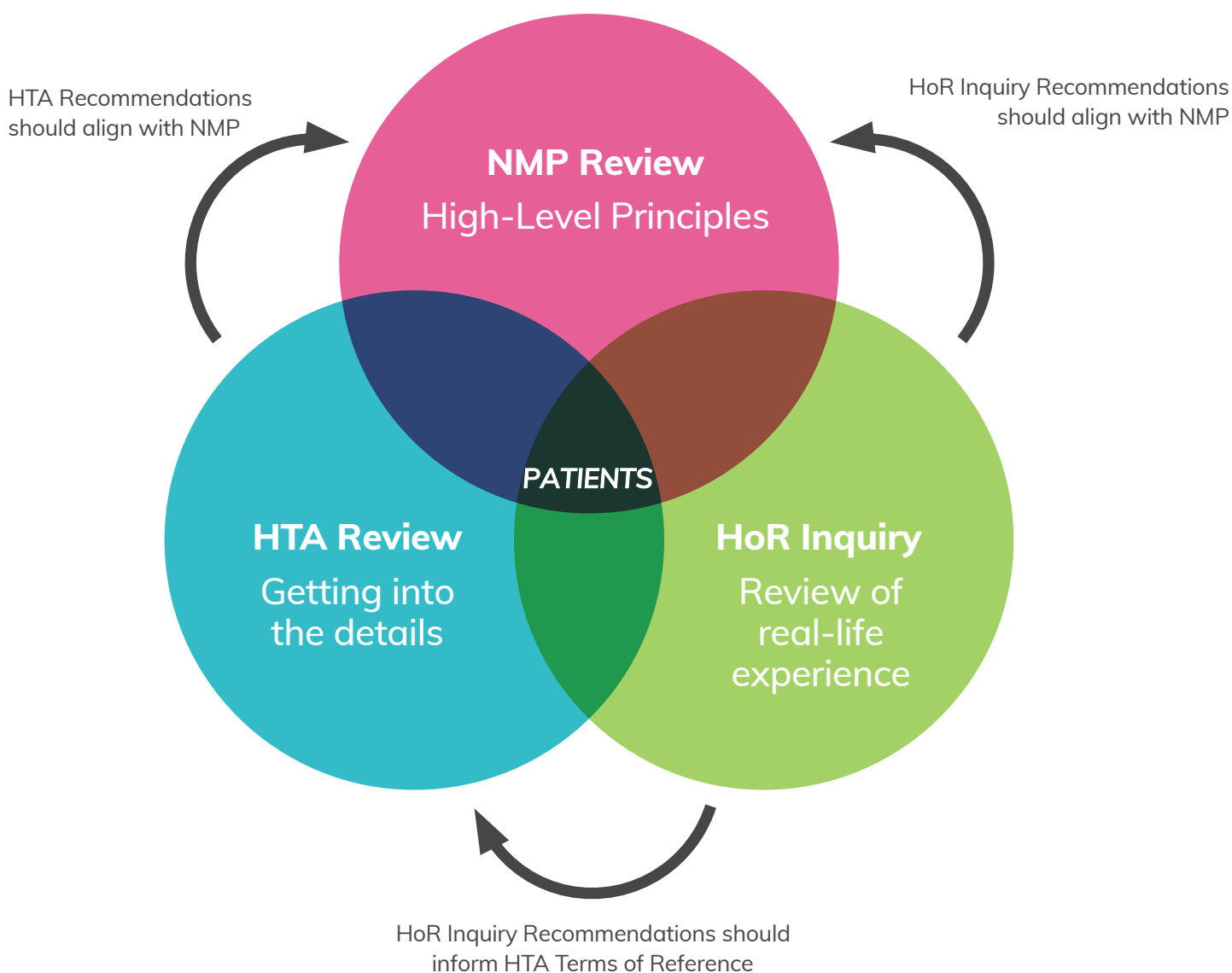
6. HORIZON SCANNING

- An annual Horizon Scanning Forum, to be run by Medicines Australia from 2022, will identify major advances in healthcare over the next 3-5 years and ensure Australia's healthcare system can adequately prepare for changes ahead of time.
- The forum will include consumer and patient representatives and their valuable perspectives to ensure their insights inform any recommendations.



Linking the HTA Review, NMP Review and HoR Inquiry

These three reviews/inquiries are all important in ensuring Australia's medicines policy is fit-for-future. They all have a different focus but should be fully aligned.



National Medicines Policy (NMP) Review

High-level policy review that will set the objectives for access to and use of medicines.

House of Representatives (HoR) Inquiry

Broad Parliamentary Inquiry into approval processes for new drugs and medical technologies.

Independent HTA Policy and Methods Review

Focused review of Health Technology Assessment (HTA) methods and policies for medicines.

It is a critical time for industry to work together in close partnership with the patient community and Government, to achieve the best possible health outcomes for Australian patients.

Further information and the full Strategic Agreement is available for download on our website.

www.medicinesaustralia.com.au