

Strengthening the PBS

Agreement with Medicines Australia on behalf of the innovative medicines sector

Purpose

Australian patients have a world class health system and access to world class medicines. With this common goal, a Strategic Agreement (the Agreement) between the Australian Government and Medicines Australia (MA) as the peak medicines industry body will support the National Medicines Policy and the sustainability of the Pharmaceutical Benefits Scheme.

This Agreement will deliver more certainty for the medicines industry through a stable PBS environment, where funding for new listings is further supported through delivering price reductions for on-patent medicines that are reaching the end of their patent life, and when these medicines come off patent and become subject to competition.

This certainty will strengthen the medicines ecosystem by encouraging companies to continue to bring innovative, life-changing, medicines to Australia, build partnerships with Australian researchers, and encourage innovator companies to invest in local clinical trials and manufacturing. This will ensure Australia remains at the forefront for the launch of new and innovative medical treatments.

The Agreement is underpinned by the shared principles of:

- **stewardship** of the health system, particularly the PBS, and a shared responsibility for its ongoing sustainability;
- **partnership** in the delivery of the National Medicines Policy;
- **stability and certainty** for the investment in innovative medicines, including recognition of the role that a predictable and stable PBS plays in encouraging investment;
- **transparency and efficiency** of processes for listing medicines on the PBS; and
- **integrity** of Australia's world class health system, including patient safety and high value clinical care.

Statement of Intent for the Government

The Government recognises the significant pressures on the health system, including a growing burden of chronic disease, an ageing population, and growing demand for high-cost, high-tech services and breakthrough medicines. It also recognises the pivotal role of the sector in delivering these breakthrough therapies that represent important advances in medicine and improve the lives of Australians.

Commitment to list new and innovative medical treatments

The Government is committed to making fiscally responsible investment decisions that are informed by the best available evidence about patient safety and improved patient health outcomes. The Government will continue its commitment to list all positive recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC).

Savings accrued from the full five years of the Agreement will be placed in the contingency reserve to support investment in new and amended PBS listings in order to maintain the Coalition's commitment to list positive recommendations of the PBAC. This reserve may be accessed at any time over the five years and may be supplemented. Initially, investments will include: anti-venoms and national stockpile costs; and new and amended PBS listings under 2016-17 Budget. Both parties will review the effectiveness and sustainability of reserved savings and explore opportunities for additional investments.

Should the cost of new and amended listings recommended by the PBAC exceed the further available savings from the Agreement, then, as with current practice offsetting savings will need to be identified, or additional funding included.

Stability for the medicines sector

The Government is committed to delivering medicine pricing certainty and policy stability for the innovative pharmaceutical industry and undertakes not to pursue further changes to PBS pricing policies during the five years of operation of the Agreement (other than those agreed in accordance with the Agreement) without consultation with the innovative pharmaceutical sector.

The Government recognises the savings already committed by the sector, and new measures will account for the impact of existing policies on price stability. In making the necessary amendments to the Act, the Government intends to seek appropriate safeguards against unintended consequences, and will also seek to limit disincentives to bring new presentations to patients.

A framework for the formation of Therapeutic groups

The Government undertakes not to pursue the formation of new Therapeutic Groups (TGs) during the life of the Agreement. The Government will work collaboratively with MA to develop a new framework for potential future formation of TGs.

Support Enhanced Transparency and Efficiency in PBS Functions

The Government commits to working with Medicines Australia to improve timeliness, transparency and efficiency in PBS listing processes. This work will include revising the associated cost recovery arrangements to better reflect the real costs of activity associated with PBS processes, consistent with the Australian Government Cost Recovery Guidelines.

Statement of Intent for Medicines Australia

MA recognises industry stewardship is important to ensure the long term sustainability of the health system, to allow for reinvestment into cost effective new medicines and to ensure a responsible and viable innovative medicines industry.

Support extended/additional F1 statutory price reductions

MA supports the continuation of statutory price reductions for pharmaceutical items on the F1 formulary, with a 5% price reduction after medicines have been listed on the PBS for more than five years (extended out to include April 2021 and April 2022), an additional reduction of 10% after medicines have been listed for more than 10 years and an additional 5% reduction after medicines have been listed for more than 15 years (commencing on 1 June 2018 until April 2021).

Increasing the 16% Statutory Price Reduction to 25%

MA supports increasing the 16% statutory price reduction to a 25% price reduction (from 1 October 2018) on the PBS listing day of the first generic or biosimilar brand competitor for a medicine.

PBS Stewardship measures

MA will work with the Government on enhancements to prescribing software that will default to the medical name in producing a prescription, while retaining physician choice in any brand preference.

MA will work with the Government on the introduction of certain measures that improve the appropriate uptake of biosimilar medicines. Such measures will be employed on a case by case basis as determined by the PBAC. Principles for prescriber choice and pharmacovigilance requirements will be retained. Both parties will review the savings due to these uptake measures and impact for patients and prescribers, with no other measures being introduced without consultation with MA.

Joint commitment to dialogue and consultation

The Agreement provides a further platform for continued dialogue and consultation for how the Government and MA can continue the important work of bringing new and innovative medicines to Australian patients through the PBS. Both the Government and MA commit to the continuation of existing discussion forums, in addition to the formation of a Joint Oversight Committee to review progress towards and achievement of the commitments in the Agreement