Strengthening PBS

Measures to Support Generic and Biosimilar Medicines Uptake

Purpose

The Australian Government and the Generic and Biosimilar Medicines Association (GBMA) have entered into a Strategic Agreement which operates until 30 June 2020, to support the National Medicines Policy and the sustainability of the Pharmaceutical Benefits Scheme, contributing to the Government's investment of $4.9 billion in new medicine listings, and providing greater certainty of Government pricing policies for F2 Formulary medicines with brand competition, in an environment of ongoing medicine price reductions associated with price disclosure.

The Agreement is underpinned by the shared principles of:

- **stewardship** of the health system and a shared responsibility for its ongoing sustainability, in particular a shared responsibility for the stewardship of the PBS;
- **partnership** in the delivery of Australia's National Medicines Policy**;**
- **stability and certainty** for industry viability, and of the Government's commitment to consult on savings from the F2 Formulary during the term; and
- **integrity** of Australia's world class health system, including patient safety and high value clinical care.

In line with this Agreement, the Government is progressing generic and biosimilar uptake drivers in consultation with GBMA.

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.

The Government recognises the important role that generic and biosimilar medicines play in terms of PBS sustainability and access to affordable medicines for consumers and is committed to working closely with the GBMA. In this regard the Government will extend the current Strategic Agreement through to 30 June 2022.

Under the Strategic Agreement, the Government and GBMA have discussed proposals to support a viable generic and biosimilar sector and increase the uptake of generic and biosimilar medicines. In recognition of these discussions the Government will implement the following measures.

Biosimilar Uptake Drivers

The Government is committed to promoting the greater use of biosimilar medicines in Australia and will support the introduction of measures that improve the uptake of biosimilar medicines as recommended by the PBAC on a case-by-case basis, including:

- recommending prescribing of a biosimilar brand for treatment naïve patients with an opportunity for the clinician to prescribe the originator biologic within the pre-existing level of authority; and
- different prescribing processes for biosimilars and reference biologics through applying a lower level of authority to the biosimilar than exists for the originator.

The Government will continue its investment in the Biosimilar Awareness Initiative in educating prescribers, pharmacists and consumers on the benefits of using biosimilar medicines through supporting the GBMA with a grant to undertake activities to further promote the appropriate prescribing, dispensing and use of biosimilar medicines.

Price Disclosure Moratorium

To ensure viability of drugs that have been in price disclosure for more than seven cycles, the Government intends to increase the discounting threshold (after which a price reduction is applied) from 10 per cent to 30 per cent.

Prices of these medicines will continue to be monitored through normal price disclosure data capture processes and the discounting threshold will revert back to 10 per cent if there is continued breach of 30 per cent discounts for two consecutive cycles.

E-Prescribing Investment

The Government intends to implement enhancements to electronic prescribing (ePrescribing) for PBS medicines, specifically, the development of a national consumer-centric ePrescribing system which would:

- support consistent approaches across prescribing and dispensing software packages that produce default prescriptions by International non-proprietary name (INN), while still preserving prescriber choice;
- improve PBS data analytic capabilities with expanded PBS core data elements
- explore capacity in software for enhanced notification on shortages and deletions;
- ensure high level of understanding and importance of pharmacovigilance principles and reporting; and
- improve real-time reporting, recording and monitoring of controlled drugs including provision of relevant information to prescribers and dispensers by means of the national Electronic Recording and Reporting of Controlled Drugs (ERRCD) IT system.

The GBMA will be a key player in the co-design of the above enhancements.

Continuation of the Generic Medicines Working Group (GMWG)

The GMWG will operate during the extended Strategic Agreement continuing to look at agreed priority policy areas which will include:

- monitoring biosimilar uptake to assess the effectiveness of implemented uptake drivers and ongoing education initiatives; and
- issues relating to price reduction flow-ons to combination items with a view to consider administrative arrangements that may be required to ensure these medicines remain available on the PBS.

Statement of Intent for GBMA

The GBMA recognises the importance of maintaining the long term sustainability of the PBS and the health system more broadly, and the essential role generic and biosimilar medicines play in providing that sustainability.

Through the Strategic Agreement, GBMA has demonstrated a strong commitment to working constructively with the Government to support the reliable ongoing supply of these medicines, and the viability of the industry that supplies them.

Biosimilar Uptake Drivers

In exchange for the measures designed to support the generic and biosimilar sector, GBMA will acknowledge the savings measures outlined within the Strategic Agreement with MA. These include:

- an increase to the statutory price reduction on PBS listing of first new bioequivalent or biosimilar brand from 16 per cent to 25 per cent;
- extending the current F1 formulary 5 per cent statutory price reduction policy beyond April 2020;
- applying an additional 10 per cent statutory price reduction to brands of pharmaceutical items that have a drug that has been listed on the F1 formulary for 10 years or more;

- an additional 5 per cent applying to brands of pharmaceutical items with a drug that has been listed for 15 years.

Continued co-operative engagement on the Generic Medicines Working Group

GBMA will continue to engage constructively with Government and the Department of Health to look at agreed priority policy areas which will include:

- monitoring biosimilar uptake to assess the effectiveness of implemented uptake drivers and ongoing education initiatives; and
- issues relating to price reduction flow-ons to combination items with a view to consider administrative arrangements that may be required to ensure these medicines remain available on the PBS.