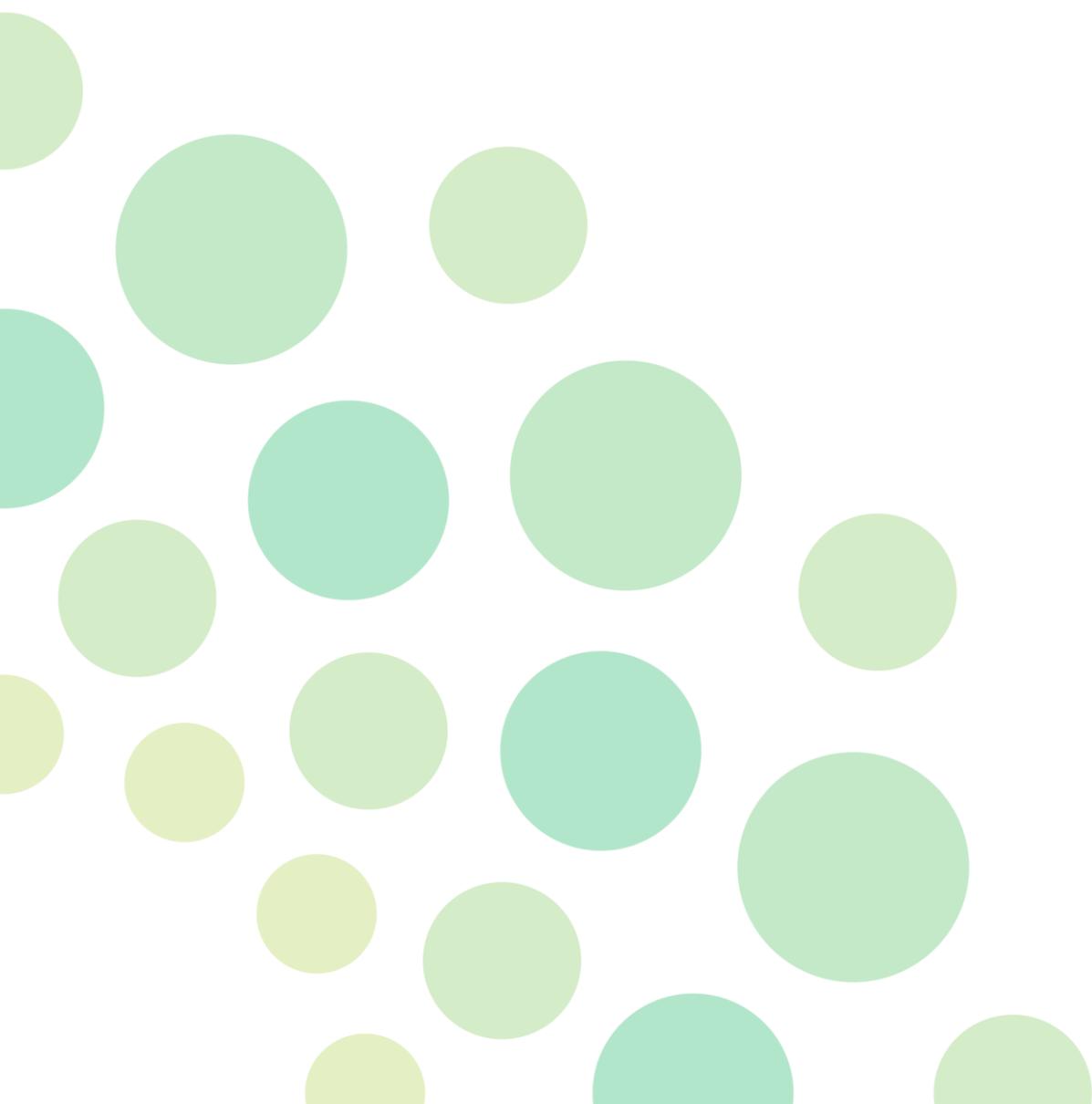




Submission
Review of Pharmacy Remuneration and
Regulation – Interim Report

June 2017



INTRODUCTION

The Generic and Biosimilar Medicines Association (GBMA) welcomes the opportunity to make this submission in response to the June 2017 Interim Report of the Review of Pharmacy Remuneration and Regulation.

GBMA sees this submission as an opportunity to build upon comments expressed in our written submission of September 2016, and during the face-to-face stakeholder consultations held earlier that year.

The options presented in the interim report must be considered in light of the landmark compacts recently signed between the Minister for Health and participants in the medicines supply chain to improve Australia's health.

In its agreement with GBMA¹, the government recognises the important role generic and biosimilar medicines play in supporting PBS sustainability and access to affordable medicines for consumers, as well as outlining proposals to support a viable generic and biosimilar sector.

So important in fact, that eight out of every ten scripts presented in community pharmacy are today filled with a generic (F2) medicine.

It is vital to ensure the options presented in the Interim Report do not threaten reliable medicines supply or the viability of the industry that supplies them. Therefore, any reform to the supply chain must support industry viability, encourage competition and ensure Australian consumers have timely access to affordable medicines.

EXECUTIVE SUMMARY

GBMA **unreservedly rejects** two options we believe will increase the risk of medicines shortages and directly threaten the ongoing viability of the generic and biosimilar medicines industry.

Option 6-1: Community Service Obligation removal, retention or replacement.	GBMA rejects the proposal that suppliers of PBS-listed medicines be obliged to ensure delivery to any community pharmacy in Australia.
Option 10-5: General medicine – Listing arrangements	GBMA strongly disagrees that tendering for generic medicines would improve supply chain efficiency and reduce costs to the Australian community.

¹ "Strengthening the PBS – Measures to support generic and biosimilar medicines update"

<http://www.health.gov.au/internet/main/publishing.nsf/Content/Landmark-compact-GBMA>

If implemented, these options would have significant negative consequences for the ongoing supply of affordable medicines, physician and patient choice, the sustainability of the PBS, and the generic and biosimilar medicines industry.

OPTION 6-1 CSO REMOVAL, RETENTION OR REPLACEMENT

GBMA rejects the proposal that suppliers of PBS-listed medicines be obliged to ensure delivery to any community pharmacy in Australia.

While the Panel notes its awareness of the significant impact of price disclosure on the profitability of pharmacies, the Panel should also be aware of the significant impact of price disclosure on suppliers of generic medicines, especially as the cost of doing business continues to rise.

In 2016, the Department of Health reviewed a list of generic medicines where the commercial viability of supplying these was at risk. In recognition of the need to support ongoing supply, the ex-manufacturer price of around 60 everyday generic medicines was increased.

Placing the onus for distribution on suppliers of generic medicines will only add to the cost of doing business. It will shift the scale towards commercial unviability and therefore cessation of supply for a significant number of generic medicines that Australians rely on to keep them well.

Imposing this requirement would have a significant impact on competition and the affordability of PBS medicines.

Suppliers of generic medicines on the PBS are not logistics experts. While a direct distribution model might be possible for large suppliers of PBS medicines (such as Pfizer), not all manufacturers are in a position to manage wholesaling, logistics and distribution of their products. The implementation of this proposal could therefore be considered anti-competitive and is not in the interest of an affordable PBS.

Without a direct distribution model, this option proposes suppliers would need to enter into distribution arrangements with third party logistics experts. These arrangements would come at a considerable cost that could not be absorbed and therefore would either be passed on to consumers or result in the medicine being withdrawn from the market.

It is important to consider the consequences of placing the onus for delivery on manufacturers as this would act as a barrier to entry for smaller and or niche/specialised PBS suppliers. As competition is what drives PBS savings through price disclosure, anything that stifles competition should be cautioned against.

Further, GBMA questions any benefit to Australian patients from implementing this option. It is difficult to see how multiple pharmacy deliveries by multiple distributors would simplify the current system and support timely patient access to medicines. Such a system would be difficult and costly to establish, administer and audit.

OPTION 10-5 GENERAL MEDICINE – LISTING ARRANGEMENTS

GBMA strongly disagrees that tendering for generic medicines would improve supply chain efficiency and reduce costs to the Australian community. Following landmark compacts reached in May 2017 between the Minister for Health and medicines suppliers to further reduce the price of generic medicines, this option is now redundant.

A tendering system for generic medicines poses more risks for Australian consumers than benefits. It will only reduce patient choice, cause medicine shortages and rationing, destroy investment in this country, and irreparably damage the sector that seeks to make medicines affordable.

Price disclosure has demonstrated its effectiveness in reducing the cost of generic medicines and delivering savings to the Commonwealth of over \$25 billion. This has been achieved through competition between suppliers. From the significant price reductions and PBS savings delivered through price disclosure, Australia now has some of the world's lowest ex-manufacturer prices for generic medicines.

Competition, not tenders, underpins the PBS pricing model for generic medicines and ensures timely access to affordable medicines.

Tenders impact medicines supply certainty

As the ex-manufacturer price of generic medicines is reduced through price disclosure, local suppliers seek lower cost supply arrangements. Australia represents only 2% of the global pharmaceutical market. Therefore, if international manufacturers are able to secure higher prices other markets, supply destined for Australia may be diverted to these more profitable countries.

Tenders disincentivise market entry

Tenders effectively lock out competition for a defined period and are not conducive to attracting and retaining multiple suppliers. As there is no certainty of an opportunity to enter the market post approval, a tender would disincentivise the number of suppliers seeking TGA evaluation and registration of generic medicines. This reduces redundancy in the system and patient choice as it reduces the number of alternative suppliers.

Tenders reduce competition

It is important to recognise that generic medicines deliver PBS savings in two ways:

- Upon market entry – statutory price cut of 16%, soon to be 25%
- Through competition and price disclosure – PBS price paid by government reduces over time.

Price Disclosure encourages competition between suppliers and reduces prices over time with the PBS is the main beneficiary. A competitive generic medicine market therefore is in the interests of the Australian government and a sustainable PBS.

Tenders reduce the incentive to challenge patents

Generic medicine companies challenge patents and where successful, open up the market in which to compete. Without any certainty that the successful litigant will be able to recoup costs once in the market, tenders disincentivise patent challenges. It is important to recognise that the government is the main beneficiary from patent challenges through the statutory price cut and ongoing price disclosure savings.

Tenders are unnecessary in the Australian context of price disclosure

There is no doubt price disclosure has been effective in reducing the PBS prices of generic medicines. With an effective mechanism in place, tenders would only pose more risks than benefits to the Australian healthcare system.

ABOUT GBMA

GBMA is the national association representing companies that manufacture, supply and export generic medicines. GBMA represents all major generic medicine suppliers in Australia and more than 90% of all generic medicines dispensed in Australia. Members of GBMA ensure all Australians are offered the highest quality generic medicines whilst providing affordable health outcomes that benefit all Australians.

The generic medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public.

The availability of generic medicines in this country helps to deliver:

- Timely access to affordable medicines;
- Substantial savings to the PBS;
- Thousands of highly skilled jobs; and
- Domestic manufacturing and annual exports of \$300 million.



GBMA
Generic and Biosimilar
Medicines Association

Making medicines affordable

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