



The Pharmacy  
Guild of Australia

## REFORMS TO THE GENERIC MEDICINE MARKET AUTHORISATION PROCESS

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Comments by the Pharmacy Guild of Australia

Reforms to the generic medicine authorisation process may be part of a proactive solution to reduce the incidence of medicine shortages in Australia

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## Background

The Pharmacy Guild of Australia (Guild) is the peak pharmacy organisation representing community pharmacy. The Guild aims to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

## Need for a robust supply of medicines in Australia

The Pharmacy Guild of Australia supports measures that contribute to proactive management of medicine shortages in Australia. The extent of shortages over the last five years continues to increase.<sup>1</sup> Medicine Shortages and sourcing alternative products is currently one of the biggest problems facing community pharmacists. The Guild is regularly contacted by members when they are desperate and frustrated at not being able to source a medicine for their patients.

Administration and the work that pharmacists are required to do to source alternative medicines is a burden on a small business. Pharmacists should not have to spend excessive amounts of time locating medicines to provide to their patients, rather their time can be better spent with their patients, providing counselling and clinical care. One of the big issues facing pharmacies when dealing with a shortage is when base price products listed on the Pharmaceutical Benefits Scheme (PBS) are unavailable or unable to meet demand, and the only product available is one with a brand price premium which can range from \$0.25 to \$35.30<sup>2</sup> on various products. Patients have no option but to accept the product with the higher price and affordability can be a problem for some patients. A report by the George Institute highlighted that 'for many consumers on fixed and lower incomes with ongoing medicines needs, co-payments can account for a large portion of their budget. There are an increasing number of reports of people choosing not to fill prescriptions, or making a choice between one medicine and another, because they are unable to afford it.'<sup>3</sup>

There is a need for proactive planning to reduce the risk of shortages occurring. While increasing generic alternatives to the current medicines inventory is one way that may assist with supply, it in itself does not provide a guarantee against shortages. We also need to actively identify known weaknesses in the Australian market and approach sponsors to address those weaknesses.

Any application made to the TGA for registration and the PBAC for listing on the PBS should be synchronised in this situation, so that the process is not prohibitive for the sponsor. Costs associated with registration and PBS listing may also need to be managed, as these too may be prohibitive for smaller companies attempting to introduce generics, particularly if introducing to market to cover a shortage for one or more products with dominant market share.

Please find below responses to those questions that are relevant to the issues mentioned above.

*Q8. Is it appropriate to offer incentives to medicine sponsors to bring more generic medicines to Australia?*

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<sup>1</sup> Medicine shortages in Australia – what are we doing about them? Australian Prescriber 2 Oct 2018; <https://www.nps.org.au/australian-prescriber/articles/medicine-shortages-in-australia-what-are-we-doing-about-them>

<sup>2</sup> PBS Expenditure and Prescriptions Twelve Months to 30 June 2018; <http://www.pbs.gov.au/statistics/expenditure-prescriptions/2017-2018/expenditure-and-prescriptions-twelve-months-to-30-june-2018.pdf>

<sup>3</sup> Re-imaging the funding wheel: Sustainable access to medicines; George Institute Report April 2017: <https://www.georgeinstitute.org.au/sites/default/files/funding-innovative-medicines-april-2017.pdf>

It may be appropriate to use incentives to address weaknesses in the Australian medicine market. These may need to be targeted, as incentives to supply generics that would result in oversupply of certain parts of the market would not be useful.

We also note that listing generics on the PBS may also result in the application of a brand premium to one or more branded products already listed and we are concerned that there may be situations where the generic is not capable of meeting demand. An example of this was when Osteomol® (paracetamol modified release 665mg) was listed as a generic to Panadol Osteo® in 2015. At the time Panadol Osteo was the highest volume product on the PBS and demand for the base-priced Osteomol could not be met. As a result, patients, many of which were pensioners, had no option but to purchase Panadol Osteo with a brand premium at the time of \$1.42.

*Q9. Should we offer incentives to medicine sponsors to address medicine shortages and medicine expenditure?*

Incentives may be a very effective way of encouraging sponsors to address weaknesses in the Australian market that may be otherwise neglected. Incentives such as reduced fees, fast tracked and synchronised applications and reduced administrative requirements may be more cost effective in the long term if they facilitate greater patient access to essential medicines.

An example of this is the prolonged EpiPen® (adrenaline per device) shortage in 2018, where patients were advised to continue to have on hand – and use if necessary – expired EpiPens. The shortage was causing distress to people with severe allergies, including parents of children with allergies.<sup>4,5</sup> Facilitating the early registration and PBS listing of an alternative brand would have alleviated much of the concern of people having to manage life-threatening allergies.

*Q10. Are there any other examples where a more robust supply of generic medicines may be beneficial to patients and the Australian health system?*

A greater diversity of available formulations would be beneficial in aiding patients with intolerances to find a version of a medicine that they are able to take.

Increase in certainty of medicine availability within the industry will enable prescribers and dispensers to prescribe and supply with confidence, resulting in less time spent sourcing treatment and more time spent with the patient providing care.

A more robust supply of generic medicines will enable proactive management of potential medicine shortages, which will reduce stress on the Australian Health system and result in better health outcomes for patients.

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<sup>4</sup> <https://www.news.com.au/lifestyle/health/health-problems/concern-in-australia-over-shortage-of-lifesaving-epipens/news-story/30b22c7180274416c39a290fcfb2c0d> ; 26 Feb 2018

<sup>5</sup> <https://www.sbs.com.au/news/australian-epipens-still-in-short-supply> 6 Aug 2018