

Pharmaceutical Society of Australia

Submission to the Post Market Review of Authority Required PBS Listings

The Pharmaceutical Society of Australia (PSA) welcomes the opportunity to provide input to the Post Market Review of Authority Required PBS Listings.

PSA is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are over 28,000 registered pharmacists in Australia, of which approximately 80 per cent work in the community sector.

The subsidisation of pharmaceuticals under the Pharmaceutical Benefits Scheme (PBS) is integral to Australia's public health care system. The PBS is a scheme that, to a very large extent, fulfils that part of the National Medicines Policy (NMP) relating to equity of access to pharmaceuticals by providing "timely, reliable and affordable access for the Australian community to necessary and cost effective prescription medicines". While Government outlays under the PBS are projected to remain stable at around 0.7% of GDP over the period to 2020, spending per person is projected to increase by 22% over the same timeframe.ⁱ The PBS remains an area of attention for the Federal Government, despite the savings made through recent reforms, and the latest Australian Institute of Health and Welfare report showing that health expenditure has reached its lowest level in 30 years.ⁱⁱ The demands on the PBS will also continue to grow with advances in medical and technological sciences, as well as increased demands from an ageing population and high rates of chronic disease.

Authority prescriptions provide a means of customising the PBS to meet the medication needs of individual patients and for a controlled introduction of drugs in a new therapeutic class or with restricted PBS indications. However, the time and effort involved by prescribers in obtaining approval, and the potential for that process to interrupt patient consultations, may provide sufficient disincentive that patient access to required authority prescription medicines is suboptimal.

Furthermore, access to subsidised medicines does not ensure that the benefits of therapy are optimised for individual patients. Health outcomes are affected by the quality of use of medicines. It is thus important that health professionals, consumers and carers are provided with appropriate information, education and support to be able to achieve the best possible therapeutic response. Without this, the true objectives of the PBS will not be met and the sustainability of the scheme will be compromised.

Similarly, the complexity of medicines and therapies requires appropriate clinical justification to ensure patient safety, selection of the best therapeutic option, and cost considerations. In some instances, this has led to multiple listings for a specific substance — for example, there are 18 separate listings for imatinib or 15 for sunitinib. This type of scenario is not particularly helpful for prescribers or pharmacists and can cause confusion or result in additional time spent on administrative tasks.

While PSA has not undertaken a detailed assessment of individual Authority Required medicines, we believe the appropriateness of current or future listings can be assessed around factors including:

- Level of risk of off-label use (i.e. outside PBS listed indications);
- Period of validity of submitted clinical evidence (e.g. whether the result of a blood test can be considered 'valid' for a longer period of time thereby permitting less frequent submission of ongoing evidence for continuation of treatment);
- Appropriate period of controlled introduction (tailored to the substance/product);
- Expert opinion or consultation on formulation of restrictions (e.g. for substances with high abuse potential); and
- Equitable access across settings (e.g. public vs. private).

ⁱ Australian Government, *Australia to 2050: Future challenges*. The 2010 Intergenerational Report

ⁱⁱ AIHW 2014. Health expenditure Australia 2012-13. Health and welfare expenditure series no. 52. Cat. no. HWE 61. Canberra: AIHW