

European Commission Directorate-General for Trade
BKP Economic Advisors
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Re: Consultations for Sustainability Impact Assessment - Negotiations on FTA between the EU and Australia

Medicines Australia welcomes the opportunity to provide additional input into the Sustainability Impact Assessment – Negotiations on an FTA between the EU and Australia.

Medicines Australia is the peak industry body representing the research-based medicines industry in Australia: Innovative companies that research, develop, manufacture and supply new medicines and vaccines to the Australian market. Our members are proud of the contribution they make to the health and well-being of everyday Australians, as well as to the local economy. Our industry provides high value jobs for Australians, generates up to \$4 billion in exports and invests over \$1 billion in research and development every year¹.

The Pharmaceutical Benefits Scheme (PBS) is an integral part of Australia's health care system. It is widely recognised as a world leader in providing consumers with equitable access to affordable medicines. Through the PBS, the Australian government, as a monopsony purchaser, determines which pharmaceuticals will be eligible for PBS listing and negotiates the most cost-effective prices. These are then subject to a range of ongoing statutory and administrative pricing policies that continuously put further downward pressure on the cost-effective price. The result is that taxpayers and consumers benefit from comparatively low drug prices. The PBS's capacity to constrain pharmaceutical expenditure affects all Australians and is not open to trade for potential economic gains in certain areas of the economy.

Conversely, spending on the PBS has been shown to be flat, and as a proportion of overall health expenditure it has been declining in the period 2010-2018 (see Figure 1).

Australia has a very robust and cost-effective process for getting medicines listed on the PBS. The Health Technology Assessment (HTA) driven, listing process in Australia requires the manufacturer to submit clinical and economic evidence to the Pharmaceutical Benefits Advisory Committee (PBAC) who are tasked with evaluating whether the medicine is cost-effective and should be included on, and thus subsidised by, the PBS.

The PBAC considers many factors during evaluation including:

- Comparative health gains
- Comparative cost effectiveness
- Patient affordability
- Predicted use and impact on PBS budget
- Impact on health budget
- Effective alternative treatments
- Equity concerns
- Ability to target the target population
- Public health concerns
- Severity of the medical condition to be treated by the new medicine

Upon a medicine receiving a positive recommendation from the PBAC, the Department of Health enters into bilateral negotiations with the medicine manufacturer regarding pricing. Once the medicine is on the PBS there are further rules governing how the reimbursed price can change, with statutory decreases at particular intervals and reference pricing comparisons to similar listed medicines and other administrative policies such as post-market and cost-effectiveness reviews of medicines, or groups of medicines.

During negotiations for the Australia-United States Free Trade Agreement (AUSFTA) some claims were made that the FTA would exert influence on Australia's ability to manage domestic health policy, ultimately undermining the PBS and resulting in higher pharmaceutical prices in Australia². However, this has been proven unequivocally to be untrue. The PBS has remained indisputably sustainable due to Australia's domestic policies and processes for listing medicines on the PBS. As the AUSFTA has not affected Australia's ability to manage domestic health policy, and PBS expenditure as a proportion of total health expenditure has been declining (see Figure 1), there is no reason to claim that any FTA with any jurisdiction will diminish Australia's domestic health policy settings.

It is evident that none of the commitments entered into in the AUSFTA have changed the architecture of the PBS, nor led to higher pharmaceutical prices in Australia, and Australia remains a sovereign entity with respect to domestic health policy. It can therefore be concluded that a free trade agreement between the EU and Australia would similarly have no effect on Australia's ability manage domestic health policy, nor would it result in different health technology assessment (HTA) or pricing processes for pharmaceuticals in Australia.

PBS % Expenditure As a Proportion of Total Health Expenditure 2010 - 2018

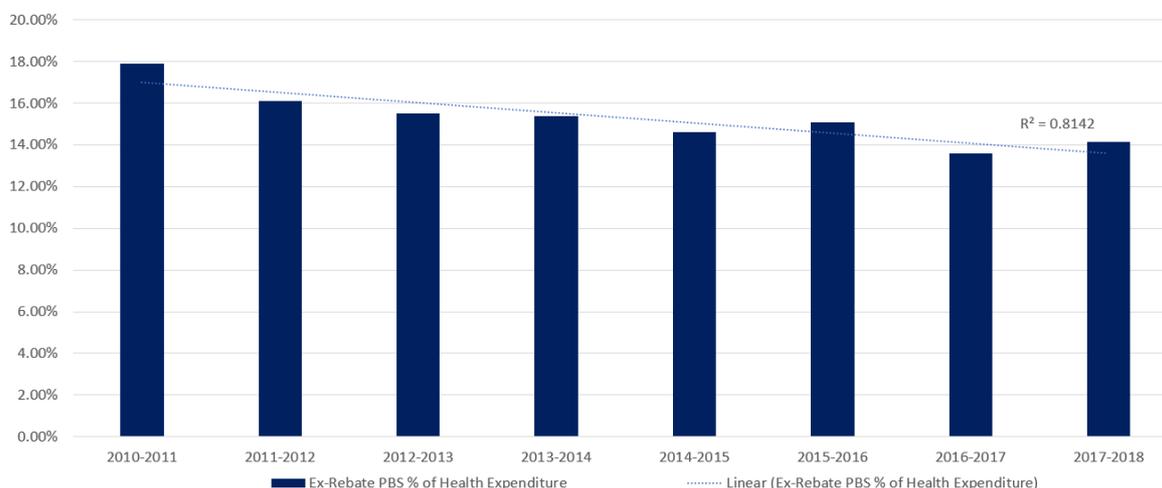


Figure 1: PBS expenditure as a proportion of total health expenditure 2010-2018

Source: Final Budget Outcome Papers, Department of Health Annual Reports



Medicines
Australia

Medicines Australia is happy to discuss or provide further comment on any aspect of our response and we would appreciate ongoing engagement and collaboration on further developments. Please contact Betsy Anderson-Smith if you would like further clarification on any aspect of our submission (banderson-smith@medaus.com.au).

Yours sincerely,

Elizabeth de Somer
CEO
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References

1. Medicines Australia FactsBook, 4th Edition
2. Parliament of Australia, Former Senate Committees. Chapter 4 – Pharmaceuticals and Health.
Available at:
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Former_Committees/fretrade/report/final/ch04