

Pfizer Australia 38 - 42 Wharf Road West Ryde NSW 2114

12 January 2018

Additional Committee Support PO Box 6100 Parliament House Canberra ACT 2600

via email: committee.sen@aph.gov.au

Dear Committee Secretary,

RE: INQUIRY INTO THE THERAPEUTIC GOODS AMENDMENT (2017 MEASURES NO. 1) BILL 2017 AND THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 2017

Thank you for providing Pfizer Australia with the opportunity to comment on the Senate Standing Committee on Community Affairs' inquiry into the above Bills.

Pfizer Australia is one of Australia's leading providers of prescription medicines and consumer health products. We manufacture medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer and manufacturer.

Pfizer Australia is a member of Medicines Australia, the peak body representing innovative pharmaceutical companies in Australia. We support Medicines Australia's submission to this inquiry and, particularly in the context of the proposed introduction of a new provisional approval pathway, encourage the Committee to carefully consider the following:

- The Bill supports more timely access to medicines for Australian patients
- The Bill will align the Therapeutic Goods Administration (TGA) with the world's best regulatory systems
- The Bill maintains the TGA's statutory focus on medicine safety, efficacy and quality
- The Bill reflects the extensive consultation undertaken during and following the independent Medicines and Medical Devices Review over the past two years
- Stakeholders will be able to review the details of subsequent regulations.

Pfizer Australia is also a member of the Australian Self-Medication Industry (ASMI), the peak body representing Australia's non-prescription medicine industry, and we, likewise, support the proposals presented in ASMI's submission to this inquiry.

Pfizer Australia urges the Committee to recommend passage of the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and the Therapeutic Goods (Charges) Amendment Bill 2017 by the Senate, with consideration given to the issues outlined by Medicines Australia and ASMI in their respective submissions.

Thank you again for the opportunity to contribute to this inquiry.

Yours sincerely,



Brian Hewitt

Head of Regulatory Affairs, Innovative, ANZ



Pamela Quane

Associate Director Regulatory, Consumer Healthcare, ANZ