Level 4, 436 Johnston Street
Abbotsford VIC 3067
PO Box 18095 Melbourne VIC 8003
Australia

Tel +61 3 9721 6000
Fax +61 3 8761 2442
www.gsk.com | www.gsk.com.au

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600
Via Email: community.affairs.sen@aph.gov.au

10 January 2018

Dear Senators:

Inquiry into the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and Therapeutic Goods (Charges) Amendment Bill 2017 (collectively, the Bills)

We refer to your correspondence dated 8 December 2017 inviting GlaxoSmithKline Australia Pty Limited (**GSK**) to make a submission to the Committee on any issues arising from the Bills.

GSK is a research-based pharmaceutical and healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer. In Australia, GSK is the sponsor of many important vaccines, prescription and over the counter medicines. GSK has a strong pipeline of innovative medicines and vaccines that it intends to register on the Australian Register of Therapeutic Goods in coming years.

GSK welcomes the opportunity to make a submission and supports the swift passage of the Bills through the Parliament in their current form. The Bills are the result of extensive consultation and negotiation between the Therapeutic Goods Administration (**TGA**), experts, peak representative groups and industry. GSK has participated in the consultation process as an independent company, via its industry representative body, Medicines Australia and the Australian Self Medication Industry Association (ASMI). GSK supports the submissions of both groups to this inquiry.

The Bills ensure that the TGA, its statutory powers and functions remain fit-for-purpose and consistent with other global medicines regulatory bodies. The Bills will benefit Australian patients through the establishment of a provisional approval process for new medicines. This important measure will ensure earlier access for patients to innovative medicines without compromising standards of quality, safety or efficacy. Importantly, this expedited approval process harmonises with the access made available to patients in comparable jurisdictions and ensures ongoing global competitiveness for Australia. GSK supports this important new measure and looks forward to using the new approval pathway to bring our pipeline of life-changing medicines and vaccines to Australian patients.

Should the committee have specific questions related to the impact of the reforms on our business and the anticipated benefits for patients please contact Carolyn Tucek-Szabo, Head of Regulatory Affairs, [redacted]

Yours sincerely

[redacted]

[redacted]

Anne Belcher

General Manager
GlaxoSmithKline Australia

Carolyn Tucek-Szabo

Head, Regulatory Affairs
GlaxoSmithKline Australia