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From the President

8 January 2018

Dr Sean Turner
Acting Committee Secretary
Community Affairs Legislation Committee
PO Box 6021
Parliament House
CANBERRA ACT 2600
Via Email: committee.sen@aph.gov.au

Dear Dr Turner

Re: Inquiry into the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and Therapeutic Goods (Charges) Amendment Bill 2017

The Royal Australasian College of Physicians (RACP) appreciates the opportunity to contribute to the Community Affairs Legislation Committee's inquiry into the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and Therapeutic Goods (Charges) Amendment Bill 2017.

We have enclosed for the Committee's consideration our previous submissions to enquiries relating to these proposed amendments, which detail the views of the RACP with respect to aspects of the reforms to the Australian regulatory framework for medicines and medical devices, including the advertising framework and the pharmacovigilance system.

Essentially, we strongly support the strengthening of the pharmacovigilance system but have concerns about the introduction of provisionally registered goods on the Australian Register of Therapeutic Goods. In the climate of continuing medical innovation, maintaining patient and public safety in the use of therapeutic goods must be of paramount priority. Any revised regulatory systems should not reduce the protections that are currently in place and working well to safeguard patient safety and promote the quality use of medicine.

The RACP is keen to be informed of the outcome of this inquiry. Should you require any further information regarding this response, please contact Bella Wang, Policy Officer [REDACTED]

Yours sincerely

[REDACTED]

Dr Catherine Yelland PSM

Enc: RACP submission to the Review of Medicines and Medical Devices Regulation 2015
RACP submission to Strengthening Monitoring of Medicines in Australia 2017
RACP submission to Therapeutic Goods Advertising Code (the Code) 2017