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03 March 2017

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir/Madam,

Re: Expedited Pathways for Prescription Medicines Consultation

I refer to the February 2017 referral of the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 to the Senate Community Affairs Legislation Committee for inquiry and report. Please find detailed below the submission from Merck Sharp & Dohme (Australia) Pty Limited (MSD).

Overall, MSD is supportive of the changes proposed in the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 (the Bill). The Bill will benefit Australian health consumers and the Australian health system overall, by delivering enhancements that ensure Australia's medicines regulatory system is fit-for-purpose and globally competitive whilst maintaining the existing statutory focus of the Therapeutic Goods Administration (TGA) on medicines safety, efficacy and quality. It will also align Australian medicines regulation with other comparable regulators.

Currently, Australian patients have to wait longer to access some medicines and other treatments than in comparable jurisdictions, which can impact health outcomes. The Bill will ensure expedited pathways for new medicines, allowing for speedier access for patients in urgent need, consistent with regulatory systems overseas.

The prompt passage of the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 will help improve the speed of access to life-changing and life-saving medicines for Australian patients and help the industry to continue to deliver important, innovative therapies to them, consistent with world's best regulatory systems. We therefore strongly support the Bill and urge the Committee to support it also and not delay its passage.

Yours sincerely,

Hamish Koss
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