rare voices
AUSTRALIA

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Submission to the Senate Inquiry regarding the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

Rare Voices Australia (RVA) is pleased to provide submission to this Inquiry. This Bill reflects the recommendations of the review of Medicines and Medical Devices Regulation (MMDR). **RVA urges the Committee to recommend that the Senate pass the Bill.**

The aim of the Bill is to ensure expedited pathways for the registration of new medicines/ medical devices for life-threatening and serious unmet clinical need. It should allow quicker access to new and innovative medicines and medical devices whilst still maintaining high levels of safety and efficacy while decreasing regulatory burden.

RVA knows how important this is for the almost 2 million Australians living with rare disease. Arguably the rare disease community has the greatest clinical unmet needs. There are only limited treatment options for rare disease (many rare diseases have no treatment options) and even where there are developed treatments, access to these treatments is uncertain and circuitous. Australians are not only being denied access to new therapies funded overseas, they are having to waiting 2-4 years longer than in comparable countries like the UK and Canada.[1] The ramifications for such delay are huge for those living with rare disease, as many life-threatening diseases progress over time.

This Bill should provide consumers with earlier access to potentially life-saving new medicines and devices. It will also support the important role of industry by accelerating their pathway to market. For rare disease treatments, the TGA is only one part of the reimbursement process however, and similar policy reform to reduce current delay experienced in PBS/LSDP also needs to be prioritised. RVA continues to call for the recommendations from the Life Saving Drugs Program to be released and for much-needed policy reform.

About Rare Voices Australia

Rare Voices Australia is a national, not-for profit Alliance that works with all stakeholders to be the unified voice and advocate for all Australians living with rare disease.

Yours sincerely

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[1] (McKell Institute 2014) Funding Rare Disease Therapies in Australia

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The unified voice for all Australians living with a rare disease