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Committee Secretary

Senate Community Affairs Legislation Committee

Parliament House Canberra ACT 2600

Submission to the Senate Inquiry regarding the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017

Research Australia is pleased to have the opportunity to make this submission to the Inquiry.

The Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 (the Bill) is an important component of the Government's continuing response to the recommendations of the review of Medicines and Medical Devices Regulation (MMDR).

The aim of the Review's recommendations was to improve the processes for the approval of medicines and medical devices by the Therapeutic Goods Administration, and to provide consumers with better information.

Schedule 1 will improve access to potentially lifesaving medicines for patients with few or no other options. In doing so, it implements a scheme that is similar to those already operating in the USA and European Union. It recognises that for these patients, the normal risk-benefit balance needs to be shifted in favour of earlier access.

Research Australia submits that the approval process provided for in this Bill achieves this, while maintaining important restrictions on the circumstances and conditions in which these new medicines will be made available. **Research Australia supports Schedule 1 of the Bill**.

Schedule 2 will provide a list of indications that can be used by complementary medicines. The objective of this Schedule is to restrict the claims that can be made for complementary medicines to a list approved by the TGA. While this appears at first glance to be a step forward, whether this is the case will depend on the indications that are included, how they are represented by manufacturers and retailers, and how these representations are perceived by consumers. There is a real risk that consumers will infer that, because a complementary medicine refers to an indication that is allowed by the TGA, the TGA is asserting the medicine is effective for this indication.

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Research Australia notes that the expert panel that undertook the MMDR also shared this concern, and Recommendation 44 of the Second Report of the MMDR sought to address this risk.

> **Recommendation Forty Four**
> The Panel recommends that where a medicinal product is listed in the ARTG under Option One (self-assessment), the sponsor is required to include a prominent disclaimer on all promotional materials relating to the product, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use.[1]

This recommendation has not been adopted by the Government. **Research Australia urges the Senate Committee to recommend the inclusion in the current bill of a clause or clauses that give effect to this recommendation.**

Schedule 3 provides a process for a sponsor to provide evidence of efficacy before being allowed to use an indication that is not on the list. This is an appropriate approach, consistent with ensuring consumers have accurate information.

Schedule 6 further supports these changes by placing controls on advertising to protect the public from false or misleading advertising. These controls will replace the current pre-approval process. Whether this is a satisfactory approach, essentially placing the obligation on the community to monitor and vet advertising claims, remains to be seen.

The success of this measure will depend on how quickly and effectively the TGA responds to complaints about advertising. **Research Australia urges the Committee to examine the TGA's plans for resourcing and implementing the complaints process to ensure that this process is effective. The TGA should also publish all complaint findings.** In addition to supporting the integrity of the process, publication will provide guidance to product manufacturers, retailers and the public about what is, and is not, acceptable advertising.

Research Australia submits the amendments contained in Schedules 2, 3 and 6 are sensible measures that support consumer choice by ensuring access to better and higher quality information about medicines.

Schedule 4 supports existing administrative practices in response to recent litigation and Research Australia makes no submissions in relation to this matter.

Schedule 5 makes further amendments to support the operation and role of Australian conformity assessment bodies in relation to medical devices that were introduced by amendments made earlier in 2017. It also makes amendments to facilitate the greater use of assessments made by comparable overseas regulators in respect of medical devices.

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[1] Expert Panel Review of Medicines and Medical Devices Regulation Stage 2 Report to the Minister for Health on the Regulatory Frameworks for Complementary Medicines and the Advertising of Therapeutic Goods 31 July 2015, page 38

Research Australia submits that the amendments in Schedule 5 are important to the effective operation of the reforms that have already been legislated and the efficient operation of the TGA and should be supported by the Committee.

Finally, **Schedule 7** introduces a more graduated and considered enforcement regime. This will better align the TGA with other similar Commonwealth bodies and should support the work of the TGA in responding to breaches and complaints. **Research Australia submits that the amendments contained in Schedule 7 will better enable the TGA to undertake its enforcement function.**

As noted above, this Bill is only one component of the ongoing reforms arising from the MMDR, which also include new regulations and changes to the TGA's processes and procedures. Together these measures are significantly improving access to medicines, and providing a more efficient and effective scheme for the regulation of medicines and medical devices.

Research Australia is willing to contribute further information and use its convening power in the health and medical research and innovation sector to respond to any further questions the Committee may have.

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About Research Australia

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our goals:

Engage

Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect

researchers, funders and consumers to increase investment in health and medical research from all sources.

Influence

government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes.

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