RESEARCH AUSTRALIA

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

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

The Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 (the Bill) is an important component of the Government's response to the recommendations of the review of Medicines and Medical Devices Regulation (MMDR). **Research Australia urges the Committee to recommend that the Senate pass the Bill.**

The aim of the Review's recommendations is to improve the processes for the approval of medicines and medical devices by the Therapeutic Goods Administration. Together the regulatory reforms are expected to reduce the administrative burden on applicants and make the approval process faster without jeopardising the safety of consumers.

Achieving this aim will provide consumers with earlier access to potentially lifesaving new medicines and devices. It is also an effective means of supporting Australia's medical device and medicines industries; by accelerating their pathway to market it will enable them to become profitable more quickly, providing them with more resources to pursue the international markets needed to be truly successful and profitable.

As noted above, the Bill is only one component of the reforms arising from the MMDR, which also include new regulations and changes to the TGA's processes and procedures. Research Australia is confident that the passage of this Bill in its current form will facilitate the other reforms required to fully implement the reforms, but achieving the outcomes is dependent on a thorough and effective consultation process on the regulations and other subsequent changes with all stakeholders.

Research Australia is also conscious that the introduction of new Australian based third party organisations able to approve new medical devices, while welcome, will require a rigorous accreditation process and compliance framework. If this is achieved, and there is no reason why it shouldn't be, the Australian community and industry will be the beneficiaries.

About Research Australia

Research Australia is an alliance of 160 members and supporters advocating for health and medical research in Australia. Research Australia's activities are funded by its members, donors and supporters from leading research organisations, academic institutions, philanthropy, community special interest groups, peak industry bodies, biotechnology and pharmaceutical companies, small businesses and corporate Australia. It reflects the views of its diverse membership and represents the interests of the broader community.

Research Australia's mission is to make health and medical research a higher priority for the nation. We have four goals that support this mission:

- A society that is well informed and values the benefits of health and medical research.
- Greater investment in health and medical research from all sources.
- Ensure Australia captures the benefits of health and medical research.
- Promote Australia's global position in health and medical research.

Research Australia would be pleased to provide any further information the Committee might require.

Yours sincerely



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