



**MEDICAL
RESEARCH
FUTURE FUND**

**Submission to the Senate Community
Affairs Legislation Committee Inquiry
into the Medical Research Future Fund
Bill 2015 and the Medical Research
Future Fund (Consequential
Amendments) Bill 2015**

About the MRFF Action Group

The Medical Research Future Fund (MRFF) Action Group was established in August 2014 to advocate for the extraordinary impact the MRFF would have on Australia's health and prosperity. The Action Group members represent a broad cross-section of the health and medical research community, including the majority of Australia's health and medical researchers in universities and medical research institutes; medical technology and bio-medical organisations; and research focused consumer health groups.

The Action Group's campaign is supported by the core peak bodies of:

- Association of Australian Medical Research Institutes
- AusBiotech
- Group of Eight Universities Australia
- Group of Eight Deans of Medicine Committee
- Medical Deans Australia and New Zealand
- Research Australia.

www.imagineahealthierfuture.org

Introduction

The MRFF Action Group welcomes the opportunity to make this submission. By focusing on the nexus between research and innovation, the Medical Research Future Fund provides an extraordinary opportunity to improve the future health and wellbeing of all Australians and to support economic growth in the key areas of medical devices and pharmaceuticals while contributing to a safer, more effective and efficient health system.

The Action Group is broadly supportive of the Medical Research Future Fund Bill 2015 (the MRFF Bill) and the Medical Research Future Fund (Consequential Amendments) Bill 2015.

As outlined below, we believe that a number of issues in relation to governance that arose with the MRFF Bill as originally introduced to the House of Representatives have been resolved by subsequent Government amendments included in the Bill passed by the House on 22 June.

This submission expresses the Action Group's support for a number of key aspects of the Bill and proposes some further minor amendments. The aim of these proposals is to further enhance the transparency of the MRFF and specifically its ability to support medical innovation. The Action Group does not propose any amendments to the *Medical Research Future Fund (Consequential Amendments) Bill 2015*.

The definitions of 'Medical Research' and 'Medical Innovation'

The Action Group supports the definition of 'medical research' as presented in the MRFF Bill as it encompasses the full breadth of research related to 'health'.

The definition of 'medical innovation' in the MRFF Bill however requires further consideration.

'medical innovation means the application and commercialisation of medical research, and the translation of medical research into new or improved medical treatments, for the purpose of improving the health and wellbeing of individuals.'

The reference to 'treatments' alone is potentially too narrow, as treatment does not ordinarily include diagnosis or prevention. As such it could exclude, for example, the development of diagnostic devices or vaccines. Similarly health economics or health services research may lead to innovation or changes in practice which are not necessarily 'treatments'.

The Action Group proposes that the definition of *medical innovation* be amended to include a reference to diagnosis and prevention as well as treatments. The following is proposed as an alternative.

'medical innovation means the application, commercialisation and translation of medical research into new or better ways to improve the health and wellbeing of individuals and the community.'

Health and Hospitals Fund

The Action Group supports the transfer of the balance of the Health and Hospitals Fund to the MRFF. The transfer enables the MRFF to be established with a sufficient balance to start providing a modest but useful amount of financial assistance to medical research and innovation in the next financial year.

The Advisory Board, Strategy and Priorities

The Action Group welcomes the establishment of an Australian Medical Research Advisory Board. The Advisory Board, which is required to have experience or knowledge in specific areas, enables expert guidance to be provided to the Government which must be considered by the Health Minister in determining financial assistance to be paid from the MRFF.

The inclusion on the Advisory Board of the CEO of the National Health and Medical Research Council (NHMRC) is also supported. As outlined in the Supplementary Explanatory Memorandum, the MRFF and the NHMRC's Medical Research Endowment Account have separate but complementary roles in supporting medical research and innovation. The NHMRC is also likely to have a role in administering some of the MRFF disbursements. The presence of the CEO of the NHMRC on the Advisory Board will support cohesion in the Government's strategy for medical research and innovation, and promote a strong relationship between the MRFF and the NHMRC.

The Action Group notes that there is no specific provision made in the MRFF Bill for the consumer voice to be represented on the Advisory Board. **The Action Group submits that community/consumer representation on the Advisory Board is desirable.**

The requirements for the Board to provide a five year Australian Medical Research and Innovation Strategy and to set the Australian Medical Research and Innovation Priorities for the MRFF every two years provide a mechanism for publicly communicating the direction and priorities of the MRFF. The Action Group welcomes the requirement that the Strategy and the Priorities be published by the Board on the internet. Given the five and two year timeframes, the Action Group queries how the Priorities can remain consistent at all times with the Strategy when there isn't always the opportunity to renew the Priorities in the same year the Strategy is renewed.

MRFF provision of financial assistance

The Action Group welcomes amendments to the legislation that require the Finance Minister to act on the direction of the Health Minister in relation to financial assistance disbursed from the MRFF Special Account under subdivisions C, D and E of Division 4, Part 2 of the MRFF Bill. We also welcome the requirement that the Health Minister must take into account the Priorities in decision making.

The Action Group endorses the flexibility in the MRFF Bill around how financial assistance from the MRFF is administered and allocated. This flexibility is essential to ensure that the MRFF is best able to achieve its broad remit of supporting medical research and innovation.

We welcome the provision in the MRFF Bill for the CEO of the NHMRC to be involved in the process of making decisions about financial assistance without requiring that all financial assistance be made available through existing NHMRC processes. This provides the opportunity for the MRFF to make use of the existing expertise and grant mechanisms of the NHMRC where these are appropriate, and to employ other mechanisms where these are better suited to funding the Priorities.

Because the remit of the MRFF to fund medical research and innovation is broader than the current NHMRC's role in funding medical research, the NHMRC is not the only relevant government body for allocating MRFF disbursements. For example, funding to support research commercialisation would be more appropriately administered by an agency with the necessary commercialisation skills and networks, and the appropriate allocation mechanisms, such as the Department of Innovation and Science. The Department of Health also administers several programs that support medical research, and is likely to be best placed to administer MRFF programs that involve other state and territory governments (e.g. matched funding to support medical research infrastructure or other initiatives involving state/territory health departments). Other programs, such as support for large pieces of medical research infrastructure, are likely to cross multiple government portfolios and jurisdictions.

The Action Group submits that public, competitive calls for applications should be the norm, contributing to transparency and impartiality in awarding MRFF research funds. Independent expert assessment of proposals for financial assistance is also important. The Action Group recognises that the expertise required will vary depending on the proposal – research projects versus commercialisation opportunities for example- but the principle of relevant and appropriate independent expert assessment of proposals is essential to ensure the most effective use of funds and ongoing public confidence in the MRFF.

The Action Group submits that clauses 20, 25 and 29 should be amended to require the Minister to obtain and consider appropriate and relevant independent expert advice in relation to a direction that amounts are to be debited from the MRFF Special Account or the MRFF Health Special Account.

In support of transparency and accountability, the MRFF Bill requires that the Health Minister report to Parliament every two years on the financial assistance provided from the MRFF. The information reported must include how the financial assistance from the MRFF was consistent with the Priorities. It must also include information about other Commonwealth funding for medical research and innovation, thus providing the opportunity to demonstrate that the MRFF builds upon current levels of medical research and innovation funding (rather than replacing it).

Clause 58 of the MRFF Bill also requires that information on amounts debited from the MRFF Health Special Account under clause 26 must be published on the internet as soon as practicable. However, the Bill does not specify what kind of information should be published on the internet. There is also no similar requirement to publish information about amounts debited from the MRFF and credited to the COAG Reform Fund under clause 20, or a grant to a corporate Commonwealth entity under clause 29.

The Action Group submits that the Bill should require that information on amounts debited from the MRFF Special Account under clauses 20 and 29 also be provided on the internet as soon as practicable, and that the information provided on the internet in respect of decisions under clauses 20, 26 and 29 should include financial details.

If a decision has been made without a public call for applications and/or a competitive assessment process, the Action Group submits that the information provided should include an explanation of why it was considered that such a process was not appropriate or necessary. Similarly, if the Minister has not received independent expert advice or the decision is inconsistent with the advice, the Action Group submits that the information provided should include an explanation for the absence of advice or reasons for the decision not to follow the advice.

Preserving the real value of the MRFF

While the MRFF Bill ensures the nominal value of the investments of the MRFF is preserved (clause 34) it does not address the erosion of the 'real' value of the capital by inflation over the longer term. We recognise that it is important that the MRFF disburses financial assistance at a reasonable level (e.g. 5%, as suggested by Government budget papers) and consistently over the long term.

In particular we note that the preamble to the MRFF Bill states

'The Parliament believes that the establishment of a perpetual fund capable of generating income over the long term is the most appropriate funding mechanism for ensuring that this fund is available on an ongoing basis.'

However, if the MRFF is to truly provide a perpetual fund that supports medical research and innovation in the long term without requiring indefinite injections of capital (the Government has indicated its intention to fund the MRFF to a cap of \$20 billion), it is essential that the real value of the capital is preserved.

The MRFF Action Group submits that in determining the maximum annual distributions under Division 2 of Part 3 of the MRFF Bill, the Board should take into account the principle that the value of the amounts credited to the MRFF from the Health and Hospitals Fund and under clause 15 are to be preserved over the long-term in real terms rather than nominal terms. This can be achieved by amending clause 34(4) a) to replace '(in nominal terms)' with '(in real terms)'.

Supporting medical innovation through investment

One of the real challenges to medical innovation in Australia when it comes to commercialisation is a shortage of suitable capital to support early stage start-up companies. This issue has been recognised recently in both the Interim and Final Reports of the Financial System Inquiry. Apart from supporting crowd-sourced equity funding, the Final Report provided no recommendations to improve the access of start-up companies to capital.¹

While recognising that the financial assistance from the MRFF Special Account can include providing capital and seed funding, there is an additional opportunity for the investments of the MRFF itself to be used to support medical innovation which is precluded by the MRFF Bill in its current form.

The Action Group recognises that the primary purpose of investing the MRFF's assets must be the generation of returns to 'enhance the Commonwealth's ability to transfer amounts in accordance with section 17' (clause 36). Nonetheless the Action Group believes there should be flexibility in the MRFF Bill for a portion of the investments of the MRFF to support medical innovation by making investments in early stage companies seeking to commercialise medical products. Such investments, as a portion of a balanced portfolio, would be consistent with the objects of the Bill, but would be prevented by Division 4 of the MRFF Bill as it is currently drafted.

The Action Group proposes an amendment to clause 36 to provide another ancillary object, which is 'to support medical innovation'. This amendment, together with clause 39 (2)(c) would then allow the responsible Ministers to provide the Future Fund Board with a direction in the Investment Mandate regarding investment in medical innovation.

The Action Group wishes to stress that it would only be a portion of the investments that could be used in this way. All such investments would be assessed on their potential to provide an appropriate

¹ Australian Government, Financial System Inquiry Final Report November 2014, p. 177-180

risk weighted return to the MRFF. Inclusion of such investments as an ancillary object would not preclude the MRFF from providing financial assistance to small innovative companies from the Health Special Account. The Medical Research Commercialisation Fund provides evidence of the commercial viability of a portfolio of investments in the commercialisation of innovative medical research.² The recent purchase of pain drug company Spinifex Pty Ltd by Novartis for \$200 million plus milestone payments provides further evidence. Spinifex Pty Ltd originated from research undertaken at The University of Queensland. Early investors included UniQuest and Uniseed (university-based commercialisation and venture capital arms) followed by some private sector venture capital; the company has also publicly acknowledged the support of Australian Government programs.³

Conclusion

The Action Group welcomes the opportunity to make this submission in relation to the MRFF, which has the potential to provide a range of benefits to the health, wellbeing and prosperity of Australians.

The Action Group believes the proposals made in this submission will assist the MRFF to better achieve its stated aims and objectives. We welcome the opportunity to provide further information in support of this submission or to discuss any aspect of the MRFF Bill further.

Contact: Greg Mullins

² www.mrcf.com.au

³ www.mrcf.com.au/blog/2015/06/australian-pain-drug-innovation-company-spinifex-pharmaceuticals-sold-to-novartis-for-us200