Science and Technology Australia

PO Box 259 Canberra ACT 2601

Re: Medical Research Future Fund 2018-2020 Priorities Consultation – Medicines Australia response to Science and Technology Australia

Medicines Australia welcomes the opportunity to provide input into the Science and Technology Australia submission into the review of the priorities for the Medical Research Future Fund (MRFF).

Please find below Medicines Australia's feedback to Science and Technology Australia for the MRFF 2018-2020 Priorities Consultation.

For further correspondence on this matter, please contact Betsy Anderson-Smith on banderson-smith@medaus.com.au or Andrew Bowskill on abowskill@medaus.com.au.

Yours sincerely,

Elizabeth de Somer

CEO, Medicines Australia

Science and Technology Australia – Medical Research Future Fund 2018-2020 Priorities Consultation – Medicines Australia response

1. **Are there any outstanding priorities from 2016-2018 that need to be extended or re-emphasised?**

- **Disruptive technology** – This priority needs to be extended and re-emphasised with a focus on next-generation treatment modalities and precision medicine. Precision medicine can mean faster diagnosis and targeted treatment, which can improve patient health outcomes, reduce waste from inappropriate treatments, and deliver savings to the health system. The pharmaceutical industry has the expertise in molecular biology and clinical research and therefore the potential to make healthcare better, safer and more cost effective. Partnerships between industry and organisations such as Australian Genomics will ensure that advancements made in pharmacogenomics and research are translated into, and informed by, clinical care.

- **Antimicrobial resistance**

- Industry plays a vital role in contributing to the prevention of antimicrobial resistance. Through appropriate incentives, industry can be involved in the development, manufacture and distribution of novel antimicrobial therapies to treat emerging resistant bacteria.
- Preventative medicine is often overlooked and is an important component of tackling antimicrobial resistance. For example, vaccines can extend the clinical utility of antibiotics by reducing the incidence of infection, thus there is a need to prioritise funding towards preventative therapies.
- From a collaboration perspective, it would be beneficial for MRFF funding to go towards innovative public-private partnerships like DRIVE-AB in Europe, whose activities include analysing new economic models for antibiotic use. This initiative helps drive research and development for antibiotics and supports commercialisation through functioning markets, whilst advocating for responsible use of medicines.
- In addition, the language in the detail for this priority should be updated to reflect the new AMR Strategy (2019-2023) which is currently in development.

- **International collaborative research** – This priority will enhance Australia's reputation as an attractive research destination, encourage and enhance the skills and knowledge of Australian researchers and ensure health system quality, effectiveness and sustainability. There is also a need to further invest in clinical trials such as for low survival rare cancers and rare diseases, as the prevalence of these diseases is low, therefore there is limited funding. The global pharmaceutical industry is an essential part of translating research and priorities should align to capture the skills, knowledge and scientific expertise of the industry.

- **Industry exchange fellowships** – This priority will enhance entrepreneurial capabilities and translation of research into commercial outcomes by strengthening collaboration with industry. MTPConnect may be able to contribute to this priority via the Bridge Program. The Bridge Program aims to transfer practical skills on pharmaceutical commercialisation through training and direct exposure to industry practitioners and is funded via MTPConnect and industry until 2019 but requires additional funding to continue. Cross fertilisation is essential

for successful translation. Fellowships between the governments and industry should be encouraged.

- **Clinical Researcher Fellowships –** MTPConnect can contribute to the expanded scope and scale of the existing NHMRC Practitioner Fellowships. Industry also has a role in increasing the translation of research into clinical practice and products of commercial potential.

- **Clinical Trial Network –** This priority should be extended as it enables collaboration between clinicians and the sharing of research capacity. There is also an opportunity to build capacity and enhance harmonisation across clinical trial networks. This creates an opportunity for Australia to become globally competitive in attracting clinical trials in therapeutically challenging areas, such as phase I oncology trials, Alzheimer's and neurodegeneration. An extension could include recapitulating the ADNet model across these challenging areas and building nationally integrated registries under the Lifting Clinical Trial and Registry Capacity stream.

- **Public good demonstration trials –** Extension of this priority will enable further investment in clinical trials in targeted areas of identified unmet need. Additional funding will assist with the translation of research into commercial outcomes. It will also increase collaboration between peak health organisations, researchers and industry.

- **Biomedical translation –** This priority should be extended and re-emphasised as it supports pre-clinical and early clinical translation of innovative collaborative health technologies, including cell therapies and advancements in precision medicine, into commercial ideas. This priority should enable industry to be consulted on priority areas and engaged throughout the research pipeline. MTPConnect can be involved with further industry collaboration in this area.

- **MRFF infrastructure and evaluation –** Medicines Australia suggests that this is ongoing administrative work to be undertaken regardless of funding, and therefore should not be re-emphasised.

  National Institute of Research – The role, function and scope of the National Institute of Research is not clear. If there is ongoing funding allocated to this priority, then the national institute should include clinical trial harmonisation in partnership with the states and territories. Industry is able to work with government to help ensure greater harmonisation and less duplication of resources.

2. **What are the unaddressed gaps in knowledge, capacity and effort across the healthcare continuum and research pipeline?**

There is a need for further recognition of the role that industry plays in the research sector. Priorities should focus on ensuring collaboration activities that are targeted to those research areas that will lead to translation of research into commercial outcomes.

- There is an unmet need in fostering greater identification and participation of patients in clinical trials. This issue is multifaceted, with one option to promote greater use of emerging technologies, including digital health and genomic testing, that will enable expanded access to clinical trials in Australia. At the moment there is little cohesion, with a coordination role

needed for the promotion of a more holistic and systematic approach to identifying patients that may be eligible for a trial regardless of their geographic location.

- Harmonisation and dissemination of the results from the priorities to each of the organisations leading the other priorities will promote further collaboration and alignment in medical research.
- There is a technical skills gap in developing intellectual property from the *in vitro* animal proof of concept stage through to the IND stage. In order to build a competitive pipeline, there is a need to accelerate commercially viable pre-clinical programs through project funding, timely access to capabilities and industry participation. Funding should be phase where continuation is subject to updated market horizon scanning to ensure the project will remain competitive over time.

- In order to meet the challenges of genomics mission and to integrate precision medicine in to the clinical practice we need to address the skills gap among healthcare professionals and in data science and computer engineering, and enable a vibrant medtech and diagnostic manufacturing industry.

To harness the genomics big data opportunities inherent in existing biobanks and patient registries a national approach to integration is needed, similar to the UK Biobank initiative.

3. What specific priority or initiatives can address any of the above deficits?

To address the unaddressed gaps identified above, a new priority should be established that focuses on industry collaboration across all priorities. This new priority will ensure that the entire health ecosystem is involved in ground breaking discoveries and will further promote partnerships between industry and research institutions. By engaging at the start of the medical research journey, future commercialisation opportunities can be identified early and promoted to ensure that our research talent remains in Australia.

Industry supports utilising the Genomics Health Futures Mission. Targeted Translation Research Accelerator, BioMedTech Horizons, Rapid Applied Research Translation and Biomedical Translation Bridge initiatives to address the technical and capabilities skills gaps.

The MRFF Funding Principles outline some points where industry has a role as a partner in collaboration and in identifying future commercial opportunities. The following table summarises some MRFF Funding Principles (that are not currently captured under the priorities) and Medicines Australia's solution to further incorporating industry input into the MRFF 2018-2020 Priorities.

MRFF Funding Principles and the role of industry in the MRFF 2018-2020 Priorities

MRFF Funding Principle	Medicines Australia's solution to incorporate industry
Funding Principle 5 - Utilise review processes that embrace diverse perspectives, including alternative disciplines, industry, healthcare and consumer experience.	An overarching industry collaboration priority should be created to ensure that, across the current other priority areas, the full health ecosystem is involved in the co-creation of health solutions. Engaging international transdisciplinary experts will ensure global relevance and competitiveness. This is particularly critical for ensuring success of blue sky opportunities funded under the

	Genomics Health Futures Mission a and Frontiers Health and Medical Research Mission.
Funding Principle 8 - Encourage partnerships in merit-based collaborative research to engage lateral and fresh thinkers and ideas, and enhance skill and knowledge combinations.	Engage and partner with industry in order to harness the extraordinary talent that is available in industry which can contribute to research. Through targeted promotion, open-up the funding opportunities to disciplines such as mathematics, data science, material science and computer, chemical, and biomedical engineering to attract skills needed to support Genomics and Frontiers missions and enable advanced manufacturing capabilities.
Funding Principle 9 - Consider favourably proposals that have collaboration, translation and scalability features to ensure the MRFF is transformative and effort is enduring.	Inclusion of a criterion within the evaluation of grants to the MRFF on previous industry collaborations and, where relevant, product innovation experience and inclusion of product development plans Consider favourably those proposals that include early clinical translation of research into commercial value.
Funding Principle 10 - Fund specific health issue initiatives assessed on scientific rigour, where there is both burden and unmet research need.	MRFF priorities should focus on global unmet research needs as identified through broad consultation. Priority should be given to funding research into rare diseases, differentiated, novel therapies such as new antimicrobials, genomics technologies, next generation treatment modalities, and precision medicine.
Funding Principle 15 - Encourage multi-government and agency, private sector and philanthropic co-investment to maximise program outcomes.	Increased opportunity for industry to access MRFF funding in partnership with research institutions to further investigate novel medicines and promote commercialisation opportunities. Funding guidelines should clarify pathways for industry participation and investment in various initiatives.

4. How can current research capacity, production and use within the health system be further strengthened through the MRFF?

It is suggested to include a criterion within the evaluation of grants to the MRFF on previous successful industry collaborations. This will assist in meeting the objective of the MRFF '*Through strategic investment, to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability'*. There is a role for industry from the beginning of the research pipeline and as a partner throughout the research journey.

Clinical trials provide patients with access to the latest treatments at no cost to Government. Industry expenditure on clinical trials is approximately $930 million per annum, out of a total clinical trial expenditure of $1.1 billion[1]. The opportunity for industry to access additional MRFF funding in partnership with research institutions will enable further investigation, development and commercialisation of novel medicines for the future.

1. MTP Connect, *Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the Sector*