AUSTRALIAN INVESTMENT COUNCIL

17 February 2022

Consultation Committee
Draft R&D Tax Incentive Determination on clinical trials
Department of Industry, Science, Energy and Resources
GPO Box 2013
CANBERRA ACT 2601

Uploaded to consultation website

Draft R&D Tax Incentive Determination on clinical trials (Phase 0-III) for an unapproved therapeutic good

Dear Sir/Madam,

As the industry association for private capital in Australia, the Australian Investment Council is pleased to present its submission to the Department of Industry, Science, Energy and Resources on the *Draft R&D Incentive Determination on clinical trials (Phase 0-III) for an unapproved therapeutic good.*

Private capital investment has played a central role in the innovation, growth and expansion of thousands of businesses and represents a multi-billion-dollar contribution to the Australian economy. Our members are the standard-bearers of professional investment and include private equity (**PE**), venture capital (**VC**) corporate venture capital (**CVC**) and private credit (**PC**) funds, alongside institutional investors such as superannuation funds, sovereign wealth funds and family offices as well as leading financial, legal and operational advisers. Our members include both Australian domestic and offshore-based firms, who in turn invest capital on behalf of millions of Australian families and attract capital from passive overseas investors.

Private capital fund managers invest billions of dollars into Australian companies across every industry sector of the economy every year. Australian-based PE and VC assets under management reached $37 billion in 2020 with an additional $14 billion in equity capital available to be invested in the short-term. Companies that partner with private capital fund managers contribute one in every nine new jobs in Australia and provide 2.6% of our nation's GDP.[1][2] The private capital industry is a significant and growing contributor to, and driver of, Australia's economic recovery and the development of Australia's industries of the future.

The Australian Investment Council is supportive of policies that foster the regeneration of growth across every sector of the Australian economy through creating jobs, driving innovation, increasing productivity and maintaining a flow of foreign and domestic investment capital.

In this context, a robust Research and Development (**R&D**) ecosystem is a critical lever for driving innovation and growing industries that will be at the cornerstone of Australia's future knowledge-based economy. To this extent, providing more clarity on the R&D framework through determinations is a positive development in generating greater clarity and certainty on eligible R&D activities for specific industry sectors over and above existing guidance material.

The Council looks forward to participating in any future discussion about the themes set out in this submission as part of the Department's consultation process. If you have any questions about specific points made in our submission, please do not hesitate to contact me or our policy team at policy@aic.co.

Yours sincerely

Yasser El-Ansary

Chief Executive

[1]Deloitte Access Economics (2018) *Private equity: growth and innovation*, April

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1. Overview

The Australian Investment Council has been a long-term advocate for policies and regulations that support the innovation economy, the growth of new businesses and new job opportunities.

The Research and Development Tax Incentive (**RDTI**) is a pivotal program for supporting Australia's innovation ecosystem and consequently, its contribution to productivity, jobs and economic growth. A strong, consistent RDTI framework is important for maintaining the confidence of Australian businesses and entrepreneurs to invest in the future of our nation. Efficient access to Research and Development (**R&D**) is also vitally important for enabling billions of dollars of investment capital to flow into Australian start-up and early stage businesses. These are the businesses that are the foundation for Australia's future growth through employment and economic contribution.

The RDTI is a critically important policy that drives large parts of Australia's innovation ecosystem and encourages investment into the development of new products and services across countless sectors of the economy. This is essential for the economic transition needed for a more knowledge-based high value-adding market. R&D is primarily invested in industries with a start-up and early stage presence with service-focused industries making the most RDTI claims dominated by scientific research services claiming the largest share of $480 million in the 2018/19 year according to data modelling undertaken by EY and commissioned by the Council.

To support this transition, our economic recovery, and Australian jobs, it is vital that businesses are able to effectively and confidently invest in new ideas and new processes. To this extent, the Council welcomed the updated R&D guidance materials released in recent months along with more guidance and examples on how the regime applies to software claims as important steps in building a more robust R&D framework.

The Council also welcomed changes to the R&D tax incentive announced in the 2020-21federal budget that would effectively give the Board of Industry Innovation and Science Australia the ability to provide determinations in order to engender greater clarity and certainty on eligible R&D activities for specific circumstances over and above existing guidance material.

The *Draft R&D Tax Incentive Determination on clinical trials (Phase 0-III) for an unapproved therapeutic good* is a very positive step in the right direction in providing more certainty on the definition of core R&D activities for businesses conducting clinical trials Phase 0-III.

The Council's responses to the draft Determination are set-out below.

2. A strong and robust R&D framework

Medical research tends to be international so there are two key operating structures for conducting clinical trials whereby either a company based offshore conducts the trials in Australia or an Australian company conducts trials for an offshore parent company.

2.1. Structure and form of the Determination

The structure and form of the Determination is a very positive step forward in creating greater clarity and certainty for what constitutes an eligible R&D activity for clinical trials in Phases 0-III. The Draft Determination is consistent with

broader industry views of clinical trials in that they must involve therapeutic goods or medical devices that are exempt from use or importation restrictions because they are being solely used for the purpose of clinical trials. This approach is also consistent with the Therapeutic Goods Act 1989, Therapeutic Goods Regulation 1990 or Therapeutic Goods (Medical Devices) Regulations 2002.

2.2. Link to TGA approvals

The Council notes that issues could arise in circumstances where the clinical trial is tied to the legislation for TGA approval. As an example, this could occur when a Chief Research Officer in Australia is conducting the trial for an offshore manufacturer, the company may not meet the TGA rules if it meets the US/Offshore jurisdictions' rules.

> Recommendation
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> Provide exemptions in the Determination to enable businesses to conduct clinical trials in Australia for an offshore manufacturer.

2.3. Exclusions

The Council also notes that the Determination excludes research that involves humanities and social science. This raises questions on whether the Determination could be read as excluding certain clinical trials for physiological disorders.

> Recommendation
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> Develop guidance for what is considered to be a clinical trial for humanities and social science.

Certain clinical trials are excluded from this draft Determination, such as R&D on generic drugs or those that would involve an excluded core activity as defined in the RDTI legislation, such as where the core R&D activity involves humanities. However, the Council notes that the draft Determination and associated explanatory materials make it clear that clinical trials that do not meet requirements in the draft Determination can still be eligible R&D activities under the R&D tax incentive law.

2.4. Specific purposes of each phase

It is important to consider the specific purposes of each phase of clinical trials. In particular, the line can be blurred between when the research phase becomes a clinical trial. Research that occurs in the pre-clinical trials may cross over into the Phase 0 or Phase I stages where there are pre-clinical studies for ethics approvals. Likewise, there will be circumstances where Phase IV Clinical Trials could fit the circumstances in the determination. For example, ongoing monitoring of COVID vaccines post initial TGA approvals.

> Recommendation
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> As pre-clinical research is harder to explain than the development phases, the Council recommends consideration be given to how this could be included in the determination.

2.5. Incongruent Legislation

The Council notes that the Board and Commissioner of Taxation operate under legislation that may be perceived to be in conflict. The Board has general determination and operates under the Industry Research and Development Act while the Commissioner of Taxation operates under the Tax Administration Act. Both pieces of legislation serve specific purposes but are conflicting in application and may cause issues for the industry participants.

While, under the Industry Research and Development Act the Board is required to act in accordance with the determination until it is found to be wrong; under the Tax Administration Act, the Taxation Commissioner is bound to a Tax Ruling, even if is wrong where taxpayers have relied on this ruling by the Commissioner before it was found to be incorrect.

Recommendation

Provide more clarity to market participants on circumstances when and where the legislation is applicable to their R&D activities.