Australian Private Equity &
Venture Capital Association Limited

26 July 2018

Joshua Toohey
Small Business Entities & Industry Concessions Unit
The Treasury
Langton Crescent
PARKES ACT 2600

Email: RnDamendments@treasury.gov.au

Dear Joshua,

Research & Development Tax Incentive Amendments

Thank you for giving the Australian Private Equity and Venture Capital Association Limited (AVCAL) an opportunity to respond to the exposure draft legislation and associated explanatory materials which outline the Government's proposed implementation of reforms to the Research & Development Tax Incentive, as well as the accompanying consultation paper which outlines key areas where the Government is seeking specific feedback.

As you know, AVCAL represents the private equity (PE) and venture capital (VC) industry in Australia, which has a combined total of around $30 billion in funds under management on behalf of domestic and overseas investors including Australian and offshore superannuation and pension funds, sovereign wealth funds, and family offices. VC and PE firms invest billions of dollars in early stage and established businesses spanning almost every sector of our national economy.

VC typically provides capital for startups and early stage companies that are looking to build and bring to market innovative products, or develop novel solutions to old problems.

These new companies are often cash-poor in the early phase of their lifecycle and must rely on a number of funding sources to get them to their next stage of growth, from which they can make significant contributions to economic and employment growth. A particularly vital source for these companies to remain viable is the refundable component of the Research and Development (R&D) Tax Incentive program.

Our submission is focused on providing views and comments in response to several of the questions set out in the Treasury consultation paper *Consultation on the draft Treasury Laws Amendment (Research and Development Incentive) Bill 2018 and Explanatory Materials*, released on 29 June 2018. In particular, AVCAL is concerned about the definition of 'clinical trials' as set out in the exposure draft legislation and explanatory material, and in relation to determining which costs can be included in that definition.

Q1. Do you foresee any implementation and ongoing compliance challenges arising from the proposed calculation of R&D intensity?

It is possible that the denominator (total expenditure) of the calculation could present some difficulty if, for the purposes of the calculation, total expenditure includes capital expenditure, which is often large and variable over time, particularly for companies in capital-intensive industries such as manufacturing. This could have the effect of changing the level of R&D intensity for those companies and therefore the offset rate from year to year. The exposure draft explanatory material states that an entity's expenditure would be worked out by reference to "accounting standards and other pronouncements issued by the Australian Accounting Standards Board," which we assume would mitigate the possibility of expenditure including capital expenses and thereby distorting the level of R&D intensity for some claimant entities.

Q3. Could total expenditure be aggregated across a broader economic group? Would this create any implementation and ongoing compliance challenges?

Current grouping rules which apply elsewhere in the R&D Tax Incentive framework (e.g. for eligibility) could also operate for determining whether total expenditure could be aggregated across broader economic groups. Given the rules are already accepted and understood within the R&D framework, this approach would provide some policy consistency for claimants, and help significantly in reinforcing a reasonable cost of compliance approach in relation to the program.

Q4. Does the definition of clinical trials for the purpose of the R&DTI appropriately cover activities that may be conducted now and into the future?

We are concerned that the proposed definition of a 'clinical trial' (based on that of the Therapeutic Goods Administration (TGA)) is too biased towards pharmaceutical products, and is outdated in that it does not allow for the inclusion of other areas of healthcare R&D that may have substantial impacts on healthcare and human health in the future. These may include such fields as medical devices (both internal and external), cell and gene therapies, genomic analyses, diagnostic technologies, and psychological, behavioural, or educational interventions.

While the definition proposed in the Treasury consultation paper specifically says that an intervention includes "a medicine, treatment or diagnostic procedures", it potentially limits the application of the definition to the above fields by specifying that:

> *[A clinical trial should have] the aim of achieving at least one of the following:*
>
> - *The discovery, or verification, of clinical, pharmacological or other pharmacodynamic effects;*
> - *the identification of adverse reactions or adverse effects;*
> - *the study of absorption, distribution, metabolism or excretion.*

Further, the definition as currently drafted will conceivably exclude trials which seek to address the overall healthcare system and that may generate increasingly important outcomes of economic benefit to the healthcare system.

Comparing other definitions of 'clinical trial' used by other jurisdictions and organisations would be worthwhile in determining a more feasible and forward-looking definition.

In the US, the Food and Drug Administration does not set out a specific definition for a clinical trial. However, a definition is provided on the ClinicalTrials.gov database,[1] which is a resource provided by the U.S. National Library of Medicine. It gives a broader definition for what a clinical trial (otherwise called an 'interventional study') is:

> *A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.*

This definition is less prescriptive than the TGA definition in terms of the range of outcomes that a clinical trial aims to evaluate by referring to biomedical and health-related outcomes.

The World Health Organisation's definition[2] also uses a more encompassing description of interventions:

[1] https://clinicaltrials.gov/ct2/about-studies/glossary

[2] http://www.who.int/topics/clinical_trials/en/

> *For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.*
>
> ***Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.*** (emphasis added)

It also speaks of 'health outcomes', which broadens the range of objectives of a clinical trial. This could again be broadened out further to include economic benefits driven by health outcomes and overall healthcare system outcomes. It would also need to be combined with the proposed definition's inclusion of pharmacological, pharmacodynamic and pharmacokinetic (absorption, distribution, metabolism, excretion) objectives to fully encompass the range of clinical trial activity.

One definition that we believe better encapsulates the range of activities that should be included is proposed below. Rather than abandoning the existing TGA definition, it is broadened out to include a greater range of activities/interventions that are studied, as well as the range of outcomes that are assessed:

> *A clinical trial is any research study that assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on:*
>
> - *health or health-related outcomes;*
> - *the discovery, or verification, of clinical, pharmacological or other pharmacodynamic effects;*
> - *the identification of adverse reactions or adverse effects; or*
> - *the study of absorption, distribution, metabolism or excretion.*
>
> *Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices (both internal and external), behavioural treatments, process-of-care changes, and preventive care.*

In our view, it would be inconsistent with the objectives of the clinical trial carve-out if the existing TGA definition were not expanded to cover other R&D activities within the life sciences that could radically change the nature of healthcare treatments and interventions in the future.

Maintaining the current TGA definition for the purpose of the clinical trial carve-out would lead to the flawed outcome of constricting R&D funding within a narrow field of research, and disincentivise the funding of R&D work in innovative and newly emerging fields of medical research.

Q5. Does the proposed finding process represent an appropriate means of identifying clinical trials expenditure for the purposes of the $4 million refund cap?

AVCAL supports the expanded authority of Innovation and Science Australia to make its findings in respect of the eligible R&D activities that qualify as 'clinical trials' binding on the Commissioner of Taxation.

It is our understanding that not all clinical trials will require findings. However, we believe that the process by which findings are deemed to be required, instigated and conducted should be made clearer. We are concerned that the delays currently being experienced by some claimants for advanced findings (sometimes up to six months) might also be experienced in determining eligible clinical trials expenditure.

One approach to this potential problem would be for the R&D Tax Incentive program to allow for claimants to claim up to the $4m refund cap and subsequently be able to apply for an extension if they were eligible under the exemption to do so. This would then allow for a full claim to be made without being held up for up to six months because of the finding process.

General comments and feedback

AVCAL believes that the proposed carve-out for clinical trials is an important step and is consistent with the points that we have raised in prior submissions regarding proposed changes to the R&D Tax Incentive. It ensures that R&D activities that require large amounts of investment over a number of years, but with potentially substantial payoffs in the form of new medical treatments and therapies, continue to be pursued, and is important both commercially and for the benefit of our communities.

However, it is necessary that guidance in determining which activities fall within the clinical trial carve-out is provided to claimants before the new rules are implemented. Furthermore, we believe that activities and expenses incurred as a result of conducting clinical trials should be deemed eligible for the carve-out.

The consultation paper states that the "carve-out is available only on R&D expenditure **incurred directly** on the identified clinical trial activity" (emphasis added). Also, current definitions and guidance around 'core' and 'supporting' R&D activities would continue to operate unchanged.

It remains unclear what 'incurred directly' would capture, and this ambiguity calls into question whether activities and expenditure that are clearly necessary but perhaps not 'incurred directly' in the actual direct conduct of the trial are to be included. Examples of such activities that may fall outside of the definition, but are nonetheless incurred as a result of a clinical trial, include: manufacturing a drug for clinical trial use; database setup and other preparatory work; internal staff time (such as senior management time within a highly research-intensive biotech company); statistical analysis; costs associated with external clinical and regulatory advisors; and report writing. AVCAL believes that these activities should be included, as they are essential for the execution of clinical trials.

Therefore, we recommend that further guidance is provided to claimants to help determine which activities are eligible or ineligible for the clinical trial carve-out, and that activities and expenditure that is incurred (though not necessarily directly) as a result of a clinical trial – including but not limited to the range of activities identified in the preceding paragraph – are deemed eligible for the carve-out within the guidance.

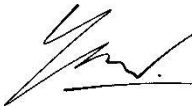
We are also concerned about the retrospective nature of the changes, especially given that commercial R&D programs typically are multi-year investments. We believe that for R&D programs and activities that have already gained approval but are to be carried out over a number of years, grandfathering arrangements should be applied that exclude them from the $4m refund cap.

We also recommend that the revised rules are implemented from 1 July 2019, in order to give companies that use the scheme time to adjust to the new rules and amend their planned R&D programs accordingly.

Next steps

We would like to thank you for the opportunity to provide a submission in response to the proposed amendments. If you would like to discuss any aspect of this submission further, please do not hesitate to contact me or Kosta Sinelnikov, AVCAL's Policy & Research Manager, on 02 8243 7000.

Yours sincerely,



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