BioMelbourne Network
ABN 30 219 606 495

Milton House
Level 2, 25 Flinders Lane
Melbourne, Australia, 3000
telephone +61 3 9667 8181
info@biomelbourne.org
www.biomelbourne.org

BioMelbourne Network
Progressing BioIndustry

19th July 2018

The Manager
Small Business Entities and Industry Concessions Unit
The Treasury
Langton Crescent
PARKES ACT 2600

RE: Treasury Laws Amendment (Research and Development Incentive) Bill 2018

Dear Sir / Madam,

BioMelbourne Network are very pleased to provide feedback and comments on the Treasury Laws Amendment (Research and Development Inventive) Bill 2018 and Explanatory Materials.

The R&D Tax Incentive Programme is a highly valued program that supports innovation undertaken by Australian businesses in the Health Industry, including pharmaceutical, biotechnology and medical technology companies.

It provides support to companies to invest in Australian R&D – employing scientists and technical staff, translation and commercialisation of medical research, undertaking clinical trials, supporting investment and encouraging the development of new products and services that deliver health outcomes to patients.

The consistent and continued support from the Federal Government is critical in maintaining and growing the jobs and exports of Australian companies in the Health Industry. The R&D tax incentive is particularly important for start-ups, spin-outs and SMEs who are in negative operating cash flow, as the cash refund allows these entrepreneurial enterprises to extend and maintain consistent R&D programs for longer. This results in a broader more robust R&D pipeline, additional product innovation and increased employment opportunities for highly skilled life sciences professionals. The result of the R&D incentive is that Australian companies have retained their ownership of intellectual property of significantly greater value and across multiple additional R&D programs than would not have been the case if they did not have access to this initiative.

The R&D tax incentive is also a significant factor in attracting foreign investment into Australia, by increasing Australia's competitiveness as a preferred location for R&D activities. There are an increasing number of Health Industry companies who are choosing to relocate their R&D activities to Australia, from places such as the US, in response to progressive policy settings such as the R&D tax incentive.

1. Reforming the Research and Development Tax Incentive

The Federal Government's review of the R&D Tax Incentive was initiated more than two years ago. However, many of the proposed policy details were only announced to the sector on Budget night in May, 2018. Many of the details of the proposed changes to R&DTI are being seen by the sector for the first time in the context of the draft legislation. Government have not widely consulted on these details prior to drafting of the legislation and the policy changes that have been proposed have not received sufficient examination to understand the implications of enacting them.

BioMelbourne Network believes that the proposed changes to the R&D Tax Incentive are complex. Implementation of these changes in the absence of detailed analysis and consultation runs a high risk of unintended consequences that will act as a disincentive to undertake high-value R&D activities in Australia.

Recent OECD statistics show that gross expenditure on R&D in Australia has fallen considerably, dropping to just 1.9% of GDP, well below the OECD average of 2.4%. While other nations across the world are making commitments to lift R&D spending, the proposed changes to the R&D Tax Incentive outlined here could have a sweeping negative impact on Australian companies' capacity for investment in R&D.

With the overall R&D spend down, BioMelbourne Network questions the intention to decrease Government support for R&D and reduce the attractiveness of Australia for R&D investment by business, especially in priority industry growth sectors.

By seeking to create a net savings by cutting support for R&D in Australia, the Government will hamper Australia's ability to be globally competitive in the area of pharmaceuticals, biotechnology and medical technology and decrease our ability to transition to an innovation intensive economy.

In terms of our overall consideration of the proposed changes to the R&D Tax Incentive, it is our view that the changes:

- Increase the complexity and introduce significant uncertainty into the program
- Have not undergone sufficient consultation to determine the impact on innovation intensive companies, such as those in the Health Industry
- Recognise the importance of clinical trials to Australia, but do not provide a fit-for-purpose definition of clinical trials
- Require greater clarity and understanding of the means of identifying clinical trials expenditure
- Have not been sufficiently modelled to examine the unintended consequences of fixing the offset at 13.5% above the company's tax rate.

- Create risk around increased burden of compliance and increased red-tape for companies that will create timing delays and deter R&D investment decisions
- Will be detrimental to Australia's ability to remain globally competitive in innovation intensive industries, such as pharmaceuticals, biotechnology and medical technology.

2. Calculation of R&D Intensity – total expenditure

There are significant potential challenges with the implementation and ongoing compliance with the proposed R&D premium for companies with aggregated turnover of $20M or more.

The use of "total expenditure" based on an Australian Accounting Standard for the calculation of the R&D intensity introduces complexity and uncertainty.

This particularly disadvantages companies who undertake both significant R&D in Australia and manufacturing activities in Australia. Of concern is the impact to manufacturers of pharmaceutical and medical technology products, who undertake significant R&D activities in Australia. Innovation is the lifeblood of the industry and the R&D intensity measure puts the success of the sector at risk.

For example: Two companies both undertake $30M of R&D, including clinical trials, in Australia each year. Company A also has a large manufacturing base, while company B has moved manufacturing activity (and expenditure) to an offshore entity. For the same level of R&D spend in the area of clinical trials in Australia, Company B will receive a substantially higher benefit based on a lower total expenditure than Company A.

This may drive the perverse outcome that Company A would be significantly better off to move manufacturing activity offshore, or to move clinical trials activity to another international location as there is minimal incentive to undertake R&D in Australia.

The complexity of predicting total expenditure is magnified for entities that are part of a consolidated tax group, who cannot estimate or influence total expenditure across the entire group. It is not possible for these businesses to predict which premium rate will be applied to their current or future activity for the rate of non-refundable R&D tax offsets, creating significant uncertainty as to the value of the Government support for these R&D activities.

This essentially removes all sense of an incentive to undertake additional R&D, as the offset will become more of a retrospective refund rather than a forward estimate of benefit. All sense of incentivising additional R&D activity will be lost and will not fulfil the policy objectives of rewarding additional R&D investment.

3. Clinical Trials exemption under the $4 million refund cap

BioMelbourne Network welcomes the exemption of clinical trials expenditure from the $4million expenditure cap. This recognises the high spill over benefits and additionality that clinical trials R&D brings to the Australian economy and to the Australian people.

However, the definition of clinical trials for the purpose of the R&DTI, as proposed in the draft legislation, is not fit-for-purpose to appropriately cover activities that are conducted now or those that may be conducted into the future.

The identification of clinical trials expenditure requires further clarification as there is significant uncertainty regarding the means to identify clinical trials expenditure for the purposes of the exemption from the $4M expenditure cap.

3.1 Definition of a Clinical Trial

The proposed definition is skewed toward pharmaceutical products and does not give adequate coverage for other forms of medical interventions such as medical devices, vaccines, diagnostics, cellular therapies, digital health, regenerative medicine, surgical procedures, genomics and health services delivery.

Right now, the future of healthcare is in flux, with new technologies disrupting traditional supply chains and care models. This means that the nature of clinical trials is evolving, and so to adequately cover the future activities, BioMelbourne Network recommends using a principles-based definition that has a broader vision and scope for clinical trials.

An existing definition that is familiar to industry may be taken from the AustralianClinicalTrials.gov.au website which is a joint initiative between the National Health and Medical Research Council and the Department of Industry, Innovation and Science:

The World Health Organization (WHO) definition for 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*'.

Clinical trial interventions include but are not restricted to:

- experimental drugs
- cells and other biological products
- vaccines
- medical devices
- surgical and other medical treatments and procedures
- psychotherapeutic and behavioural therapies
- health service changes
- preventive care strategies and educational interventions.

Researchers may also conduct clinical trials to evaluate diagnostic or screening tests and new ways to detect and treat disease.

BioMelbourne Network recommends that the proposed definition of a clinical trial be reviewed and refined through consultation with industry to ensure that the definition appropriately covers activities that may be conducted now and into the future.

3.2 Clinical trials expenditure

There is significant uncertainty regarding the means to identify clinical trials expenditure for the purposes of the exemption from the $4M expenditure cap.

The carve out is available only on R&D expenditure ***incurred directly*** on the identified clinical trial activity. However, the nature of clinical trials are quite diverse and often the design is completely unique for the proposed clinical interventions and R&D that is being undertaken. There is wider variation in the methods used to undertake clinical trial R&D activity, and it is not clear to the sector how "incurred directly" will be consistently and transparently applied in a standardised way without further guidance.

BioMelbourne Network recommends that clinical trials expenditure would include, but is not restricted to:

- Contract Research Organisation (CRO) services
- Supply of clinical material for the purposes of the study, including manufacturing, packaging, labelling and transport of materials.
- Regulatory and compliance costs
- Staff time directly associated with clinical trial activity, including designing monitoring, managing, supervising, assessing, analysing, communicating and directing clinical trial activity.
- Assay development for the assessment of clinical trial safety and efficacy endpoints
- Engagement and training of clinicians and clinical research personnel, including investigator meetings, clinical conferences, clinical advisory boards and chief medical officer services.
- Statistical and data management related to clinical trial design, delivery and analysis.
- Legal and financial services and insurance costs directly associated with clinical trial activity.

4. The new rates for the R&D Tax offset

The new R&D tax offset rates decrease the support and reward for R&D activity and do not act as an incentive for more or additional R&D investment. The changes to the rates have not been widely consulted on or sufficiently modelled to examine and test for unintended consequences of the rate changes for innovation intensive businesses.

Of particular concern for biotechnology and medical technology companies is the fixing of the refundable R&D Tax offset at 13.5% above the company's tax rate, which translates to a reduction in the rate from 43.5% to 41%, which has a material impact on the R&D

These changes will have a disproportionate impact on the smallest and most vulnerable companies, such as start-ups, spin-outs and SMEs, who make up a majority of companies in Australia's biotechnology and medical technology sectors. These spirited entrepreneurs are engaged in commercialisation activities that seek to transform Australia's ideas and discoveries into valuable products and services that benefit patients and create better health. The proposed reduction in the R&D tax offset will have a real negative impact on the ability of BioMelbourne Network members to develop and deliver health products and services to the Australian public.

For example: A medtech company with an aggregated turnover less than $10M has a forecast spend of $3M on R&D. This company will experience a decrease in the refundable R&D Tax offset from a fixed 43.5% to a rate of 41% (27.5% + 13.5%), corresponding to a cut of $75,000 to their refundable R&D Tax Incentive.
This will result in the company reconsidering staffing hires, lose one R&D engineer from their team, due to the decrease in the R&D Tax offset rate, and will defer commencing a key new R&D project.

The impact will be loss of jobs, a decrease in R&D activity and a slowing down of innovation in high potential growth stage companies in the Health Industry.

5. Applying the legislative elements of the R&DTI reforms from 1 July 2018

BioMelbourne Network does not support the retrospective application of the legislative elements of the R&DTI reform from 1 July 2018.

The changes to the R&D Tax Incentive program have a material impact on cash flow management and planning for business activity, particularly for innovation intensive start-ups and growth-stage SMEs who are at the early stages of commercialistion.

R&D activities that are currently being undertaken should not be subject to retrospective measures that decrease the level of support available to companies. The R&D required to take a health innovation to market is a long and complex process and companies will have planned their R&D expenditure and activities several years in advance. With the introduction of the proposed changes, many companies in the sector are facing lower-than-expected refundable R&D Tax offset for activities that they have already commenced, or have committed to undertake. This creates vulnerability for companies unable to mitigate the material impact of the retrospective application of changes to the program.

Given the complexity of the proposed changes and the lack of appropriate guidance at this time, BioMelbourne Network recommends that transitional arrangements are put in place with an appropriate phase-in period.

This submission has been made on behalf of the members of the BioMelbourne Network,

Dr Krystal Evans
Chief Executive Officer
BioMelbourne Network

BioMelbourne Network
Progressing BioIndustry

Milton House
Level 2, 25 Flinders Lane
Melbourne Australia 3000