BioMelbourne Network
Progressing BioIndustry

The Manager
Business R&D
Department of Industry, Innovation and Science
GPO Box 9839
CANBERRA ACT 2601
Closing date for Submissions is **Friday 28 October 2016**.

RE: Comments on Review of the R&D Tax Incentive, Recommendation 3

Thank you for the opportunity to provide feedback on behalf of the BioMelbourne Network Clinical:Industry Working Group to the 'Review of the R&D Tax Incentive'. This submission is made on behalf of the BioMelbourne Network Clinical:Industry Working Group. The working group consists of representatives from healthcare providers, clinical research organisations and specialist consultancy service providers who are actively engaged in Australia's clinical trials sector. The purpose of this group is to promote and support Melbourne, Victoria and Australia as a globally competitive and attractive location for world class clinical trials.

The R&D Tax Incentive program has been extremely valuable in broadening the economic value in research and innovation. It has encouraged collaborations between industry, universities, research institutes and healthcare facilities (hospitals). Furthermore it has preserved R&D activities and motivated organisations to retain these activities in Australia. In short, it has been achieving policy outcomes of increasing the level, additionality and intensity of R&D activity of organisations in the biotechnology, medical technology and pharmaceutical sector.

Through focussed business development initiatives, the clinical research landscape in Australia has developed into a dynamic, vibrant and growing community resulting in an environment boasting quality facilities, skilled workforce and has enabled Australia to be globally competitive for conducting clinical trials. The increasing number of collaborations between clinical research sites and industry in recent years has been very encouraging, and all indications are that growth in clinical trial activity is increasing. There are an increasing number of international companies from countries including US, China and Japan, who have chosen to relocate operations to Australia as a preferred site for investment in clinical trials R&D activity.

The proposed Recommendation 3 of the Review Paper, introducing a cap of $2M on the cash refund has the potential to compromise Australia's ability to remain internationally competitive as a preferred clinical R&D location. The R&D Tax Incentive is one feature that

attracts international companies to relocate and conduct clinical trials in Australia and is a key decision factor for securing "footloose" global R&D clinical trial investment here.

One of the critical and most expensive components of any drug/device/therapeutic development program is the clinical development stage. Australia has been very successful in securing an increasing number of Phase I trials to take place on our shores. Conducting Phase I of a clinical development plan builds the foundation for the next phase of planned clinical trials. With the complexity and intense monitoring requirements of a Phase I trial they tend be more require a greater level of investment than the later phases of a trial on a per patient basis. It is not unusual for a Phase I oncology to cost between $35-50K per patient. With 12-16 subjects in a trial, the cost quickly amounts to $900K. Phase I also tend to be shorter in duration and more than one trial may be performed and/or initiated in one year.

An example of this is in the development of an oncology product, oncology being one of Australia's key strengths and areas of world leading expertise. This usually involves investigating the product in a number of tumour streams with clinical trials being performed in tandem – an expensive but necessary requirement. Introducing a $2M cap on the R&D Tax Incentive would significantly impede the development of new oncology products and reduce our ability to attract these types of studies to Australia. This would reduce the access of Australian patients to cutting-edge technologies and the newest cancer therapies.

Introducing an R&D Tax Incentive cap would create disadvantage as a significant number of start-up to mid-size companies would not have the capital to progress with further clinical development work not only limiting additional investment in this sector but also slowing down their progress towards market. This would reduce the translation of Australian research into clinical outcomes, which impacts companies, patients and the healthcare system.

A decline in the level of clinical trials in Australia would result in the loss of other potential benefits associated with performing clinical trials here. Trials provide direct benefits to patients by offering them:

- the opportunity to access the latest interventions free of charge and before they are made available to the general public
- The chance to play an active role in their own health care and gain a greater understanding of their disease/condition
- Access to alternative therapy that would otherwise not be available to them
- Closer monitoring of their condition, care and treatment
- Participate in the early development of a product thereby educating them about the clinical trial process

Clinical trials are also valuable for patients with rare or difficult-to-treat conditions for which there may be limited evidence and option for how the condition is best treated or managed. A clinical trial may represent the only treatment choice, for example, with drug-resistant cancers where tumours are not responsive to currently available treatments. To

reduce the clinical trial activity in Australia will narrow the treatment options for patients who have exhausted all other available avenues.

The R&D Tax Incentive also encourages additionality and enhances spillover benefits in the sector. If an international company chooses to relocate operations to Australia as a clinical trial destination for their early development work and has a good experience, they will continue to involve and invest locally as the development lifecycle of that product continues.

In summary, the BioMelbourne Network Clinical:Industry Working Group strongly objects to recommendation 3 as it will significantly impact our ability to maintain Australia's standing as a world class, globally competitive and commercially attractive destination to perform clinical trials. It will significantly reduce our ability to offer patients access to emerging therapies and limit our ability to be at the forefront of healthcare technology development.

We advise that Recommendation 3 not be accepted by the Government in their response the R&D Tax Incentive Review paper.

Submitted on behalf of the BioMelbourne Network Clinical:Industry Working Group.

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