ARCS AUSTRALIA

Professional Development in Therapeutics™

26 July 2018

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

By email: RnDamendments@treasury.gov.au

Dear Sir/Madam,

ARCS Australia's Response to the Consultation on the draft Treasury Laws Amendment (R&D) Bill 2018.

ARCS Australia welcomes the opportunity to comment on the Research and Development Tax Incentive Legislation Amendments. We understand the policy position that looks to improve the integrity of the R&DTI to ensure that ineligible company applications are denied. We also understand that these changes are designed to ensure support for smaller research intensive companies and larger companies who are primarily focused on innovation.

ARCS Australia is a ARCS Australia Ltd is a national, membership-based organisation focused on the development and growth of the healthcare sector. ARCS provides education, career pathways, professional development and advocacy to the healthcare sector.

Our membership is made up of individuals working in regulatory affairs, clinical research, health economics, medical information and other disciplines who work in the development and quality use of therapeutic goods. ARCS members are based in industry, academia, medical research institutes, government, hospitals and patient groups.

Through its members ARCS has a broad and effective reach throughout the healthcare sector, and provides a neutral forum to develop, agree and implement aligned policies and initiatives.

Given the broad reach of our membership, our recommendations are aimed at ensuring Australians have access to innovative drugs and therapies.

We also understand that many sectors accessed the R&DTI program where innovation to the benefit of Australians was not necessarily their primary objective, rather to seek refund on activities that reduce the cost of risk in building their businesses.

Whilst the proposed changes will ensure these companies do not benefit inadvertently from the refund, companies in our sector, which are, by necessity, highly innovative, will be disadvantaged. This could have a detrimental affect on the Australian healthcare sector and the companies, both Austraalian and international, who work to bring these innovative products to market.

In view of the changes that have been put forward in the draft legislation, and on behalf of our members, we believe there has been insufficient time to fully understand the implications of the proposed changes and given the complexity of the R&DTI, we are not able to ensure that this legislation would not catastrophically affect the healthcare sector. We are more than happy to work with the government to more fully test the draft changes – we would need more time to undertake this activity.

More specifically, we note the following points from the draft provided:

1. Changes to the R&DTI

Will cause uncertainty to the pharmaceutical, MedTech and Biotech sector globally and could have a significant negative effect on decisions to invest in Australia by overseas companies. This would be particulary felt in the clinical research area.

2. Definition of research intensity vs total expenditure

The calculation of research intensity as drafted is confusing with the calculation derived from different standards and could be misinterpreted.

As an example, the way the calculation is made, it may be disadvantageous for large companies who are undertaking commercial activities and well as research.

3. Definition of Clinical Trials

By drafting a definition of clinical trials (from TGA) into the legislation, future changes to this definition would require legislative approval. We also consider that the definition as provided by TGA is not currently appropriate for types of trials already underway in Australia and given the diverse changes in the way clinical trials will be run in the near future, this definition would not be appropriate.

As well, there are many activities associated with clinical research that are not captured in the definition mentioned above. Many of the Australian and international companies undertake a range of activities that contribute to clinical trials and these are important but may not be captured.

ARCS Australia and the other peak bodies active in our sector have discussed these changes and have expressed similar concerns.

We ask the government to consider the above points as well as the points raised by our other peak body colleagues from our sector, for which we have consulted and concur with their position.

We thank you for your consideration.

Dr Shanny Dyer
Chief Executive Officer
ARCS Australia Ltd.