
# AusBiotech submission in response to the Consultation on the draft Treasury Laws Amendment (Research and Development Incentive) Bill 2018 and Explanatory Materials

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Introduction

As the Australian representative body for one of Australia's most innovative industries - the biotechnology or life sciences industry - AusBiotech is pleased to have the opportunity to comment on the draft legislation, despite its disappointment and frustration that the Research and Development (R&D) Tax Incentive programme is again under serious threat, and therefore so too is Australia's competitive advantage in biotechnology and clinical trials.

The R&D Tax Incentive (RDTI) is the most critical program in supporting the Government's stated policy objective – to improve Australia's performance when it comes to the translation of R&D.

In an increasingly globalised world, where capital can move freely to the most encouraging and supportive jurisdictions, sending the right signal on this centrepiece policy is critical.

Despite the welcome protection of clinical trials in the RDTI reform package, biotech start-ups will be unexpectedly hit with a 2.5 percent loss of refund (5.75 percent effective reduction in support) - a critical blow for start-up and spin-out companies commercialising medical research that has typically come from our medical research institutes and universities.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies (400 therapeutics and diagnostics and 865 medical technology companies) and employs in excess of 69,000 Australians.

The new calculation method of the RDTI benefit will see start-up biotechs with turnover under $20 million and in tax loss, lose a much-needed portion of their cash refund. Eligible expenditure, previously resulting in a 43.5 percent claim, will now be eligible for only a 41 percent refund. For each $1 million of expenditure, the loss of cash-flow will be $25,000 (this is a 5.75% effective reduction in support).

These vulnerable enterprises developing new therapies, devices, vaccines and diagnostics rely on a unique business model where they need intensive and large cash amounts to fund pre-clinical and clinical trials to reach regulatory approval and patients.

We urge the Government to consider and model the potential damage that will be caused to this burgeoning sector and the negative impact on its work in clinical and pre-clinical trials, if this legislation pushes ahead in its current form.

In addition to the new calculation method of the RDTI benefit, the life sciences sector is concerned about three further key issues:

- The definition of clinical trials is not yet fit-for-purpose as it is poor for clinical trials (CTs) for technologies other than pharmaceutical developers;
- The mechanics of the carve out for CTs has many unanswered questions about what constitutes eligible expenditure;

- Larger companies in the sector (turnover over $20 million) are grappling with the impacts of a new intensity measure that will see a reduction in support for the majority, a significant layer of complexity and uncertainly about the eligibility threshold until after R&D spend has been made, thereby eliminating the 'incentive' component.

AusBiotech has repeatedly noted that despite claims of cost blow-out made in the Review of the R&D Tax Incentive 2016, there is no problem for government to solve. Costs are (a) overstated by $0.5 billion to $1 billion [(1)]; and (b) latest figures show a drop in expected cost of RDTI of $128 million in 2017 and $698 million over forward estimates. The Government has not adequately addressed these discrepancies and appears to be pushing ahead regardless of the rationale.

In contrast, the annual Australian R&D expenditure by businesses declined by more than $2 billion (12%) per annum between 2013/14 and 2015/16 (the latest period for which data is available) [(2)]. It is now at levels not seen since the global financial crisis. This is clearly not the time to hit vulnerable companies in growing sectors of the future.

Furthermore the 'savings' that government believes it will capture by reducing claims will in fact only result in a small portion saved, as the impact of dividend imputation and the tax treatment of commercialisation revenues, for example, that operate outside of the RDTI effectively claw back this support. The RDTI will always be only a timing difference by pure design, moving the point of support earlier in a company's cycle.

The critical benefit of the program is the timing and up-front cash-flow benefit of the refundable component, when companies in loss have their highest costs (that of R&D), and this is the time that start-ups are at their most vulnerable.

R&D in the biotechnology sector is unique, both in its development challenges and in its output products. It is IP-based, heavily R&D intensive and a highly globally-mobile industry. It is highly regulated, requiring lengthy and expensive CT data before it can be approved and has longer than usual development times. It can take 10 – 15 years and up to $2.5 billion to bring one biopharmaceutical product from early research to market, with little or no revenue. Its products provide the greatest public good; from cancer treatments to helping people hear, they are life-saving and life-enhancing.

Australia is world class in biomedical research, but it needs the MTP industry to commercialise such research in order for the benefits to reach patients. As in many first world countries, in Australia, therapeutics development in Australia is a public/private compact. Typically, should the research, which is publicly funded in universities or medical research institutes, show promise as a therapeutic, it will enter a translation process that relies on the attraction of private money. Given no Australian government has ever brought a product to market, the public/private compact is activated. The task ahead is to attract the hundreds of millions of dollars required over the 10+ years of the clinical trials and development that it takes to make a therapeutic.

*(1) AusBiotech submission to the Review of the Research & Development Tax Incentive, https://www.ausbiotech.org/documents/item/187, 29 February 2016*
*(2) Australian Bureau of Statistics, Cat. No. 8104.0 – Research and Experimental Development, Businesses, Australia, releases for years 2007-08 to 2015-16.*

The OECD (2014, *Review of Innovation Policy, Netherlands*) contends that re-winding tax incentives can be damaging and a long-term approach is in this regard does increase R&D, particularly for small companies. The OECD said: "For countries that have experienced a large number of R&D tax policy reversals, the impact of R&D tax credits on private R&D expenditure is greatly diminished. It is therefore important that governments do not repeatedly tinker with such policies to minimise policy uncertainty for firms."

**New calculation method of the RDTI benefit**

It is noted that the mechanics of the new calculation of the refundable offset benefit will now be in two separate parts: the relevant corporate tax rate added to a 13.5 percent benefit. The refundable component of the RDTI will be 13.5 percent and the applicable corporate tax rate companies eligible for the refundable component is 27.5 percent – adding to a 41.0 percent claim and if in tax loss refund. This is a 2.5 percent loss that of refund that will be incurred by SMEs.

The corporate tax cuts, which are of great benefit to many SMEs, are of no benefit to companies that don't yet pay tax as they have no or little revenue, or are in loss position like many biotech companies. Therefore, we have a perverse situation where companies are disadvantaged in exchange for a benefit they are not able to access.

The RDTI has been hugely-successful in helping accelerate commercialisation of medical research by attracting pivotal investment funds and fostering a strong Australian medical technology, pharmaceutical and life sciences R&D sector, which underpins better health outcomes for Australians, encourages long-term investment that creates highly-skilled jobs, attracts clinical research and grows the economy.

Companies in this sector reinvest their refunds in R&D (CT) programmes. The proposed cut to support will be keenly felt in this sector and will force companies to raise more capital to complete their R&D programmes, or worse, delay their CTs to spread the need for capital over time (i.e. reduce additionality).

**Clinical trials exemption**

AusBiotech advocated for and welcomed the recognition of the critical role that R&D expenditure plays in clinical trials for developing life-changing and saving medicines, therapies and medical devices, with the exception from a $4 million cap. In theory, the CT exemption will give Australia an opportunity to build on its hard-won momentum in CTs and continue its growth in commercialising medical research. In practice, the proposed definition and the confusion about which expenditure related to CTs would be eligible is completely unresolved and confusing. The imposition of the $4 million cap ought to be delayed until this can be resolved.

There has been much discussion about the definition of a clinical trial for the purposes of the exception and the consultation materials note that for the purposes of the RDTI programme, the proposed definition is based on that of the Therapeutic Goods Administration (TGA): "*A clinical trial is a planned study of the safety or efficacy in humans of an intervention (including a medicine,*

*treatment or diagnostic procedure) with 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.*"

- **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?**

AusBiotech finds that the avoidance of doubt, the definition is well articulated for pharmaceutical related CTs but is unclear and unsympathetic to medical device CTs. It is understood that the policy intent was to include medical devices and future therapies and health interventions; and on that basis the definition offered is inadequate and unfit for purpose. We would support either additions to the proposed definition or the World Health Organization (WHO) definition for a CT, which 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*."**

Either way the final definition will benefit from the added articulation of areas covered, such as is shown on the Federal Government's CT website (https://www.australianclinicaltrials.gov.au/what-clinical-trial), which notes that CT 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.

Medical devices in this context, includes diagnostics or screening tests and new ways to detect and treat disease and "software as a medical device", which has a definition recently published by the TGA.

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

While the we have no comment on the finding process itself, the application of the carve-out that "is available only on R&D expenditure incurred directly on the identified clinical trial activity" is causing significant confusion and concerns.

The explanatory materials note that "current definitions around core and supporting R&D activities, as well as the requirements around overseas expenditure, will continue to operate unchanged", however many other questions remain unanswered. One example is how will a claim be treated if it encompasses both pre-clinical and clinical trials that together exceed the $4 million cap?

**Intensity measure**

Larger companies in the sector are grappling with the impacts of a new intensity measure that will see a reduction in support for the majority, a significant layer of complexity and uncertainly about eligibility added.

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

The AusBiotech consultation has revealed concern about calculating the benefit upfront as it will be impossible as total business expenditure will be unknown, and that this is turn does not support additionality or business planning. There were also numerous comments from companies that will be worse off, despite significant intensity and expenditure, and that the complexity of the measure is unwelcome. The calculation of the intensity measure has prompted an expanse of questions that are not answered by the definition provided.

Furthermore, AusBiotech contends that the calculation will disadvantage companies that have expenditure (and invest in) other activities, notably advanced manufacturing, in Australia. This expenditure should be encouraged, rather than discouraged – and we find it another unwelcome consequence of the proposed intensity measure.

**Summary**

The R&D Tax Incentive has been a game-changer for Australian innovation, especially biotechnology. It has been well targeted to assist and get benefit from this sector and the refundable component is critical to the growth of life sciences innovation in Australia. Preservation of the existing incentive is top-of-mind in R&D-intensive industries.

Australia's international competitiveness will be compromised by the Government's efforts to reduce the programme with the intensity measure, which is part of a package of benefits that attracts clinical trials and R&D investment to Australia.

Canada and the UK have attractive R&D tax incentive schemes, but Australia's offering as a package is the most attractive, which also highlights the importance of maintaining international competitiveness. However, the threat to the programme and the proposed limits will impact Australia's competitiveness in this regard.

AusBiotech has warmly welcomed the Government's recognition of the value of commercialising biomedical research via CTs and the National Science and Innovation Agenda (NISA), the Medical Research Future Fund's Biomedical Translation Fund, the medical technologies and pharmaceutical Industry Growth Centre (MTP Connect) and the importance of CTs to our country. However, we find this reform package is at odds with this Government's industry policy, especially the 2.5 percent loss of refund for SMEs.

AusBiotech is acutely aware of the difference that can be made to innovation stimulation with the right policy settings and conversely the damage to the growth of an industry from poor public policy and constantly changing provisions or threats to programmes.

The proposed package does not support the typical biotech SME, the engine room of Australian biotechnology, and in fact disproportionally disadvantages the sector, and in turn will impact the entire development pipeline and ecosystem in Australian life sciences. Any measure that compromises SME growth is unpalatable and nonsensical.

AusBiotech argued for a refundable tax incentive for some years and it is the prevailing view that the programme has done what was intended in stimulating and attracting CT activity.

Australia has excellent potential to be a nation driven by bio-innovation and our tax policy settings provide us with an opportunity to encourage growth where we want it to happen. We need a business tax regime to support the innovation ecosystem, both at start-up phase and throughout the lifetime of a company to retain international competitiveness. Our competitors and major trading markets have acted and many have more attractive arrangements for innovative companies commercialising medical research and developing intellectual property.

Concern remains over the overstating of the cost of the program, which appears to be the justification driving the narrative for change.

AusBiotech urges the Government to analyse and model carefully any move to limit or reduce the R&D Tax Incentive programme, especially where it is making great gains, lest tinkering undermines the programme and undoes the hard-won momentum in innovation in Australia.