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19 April 2010

Dear General Manager of the Business Tax Division

*Submission in response to the 'second exposure draft' of the Tax Laws Amendment (Research and Development) Bill 2010, released 31 March 2010*

Please find following the AusBiotech submission, which encompasses feedback from consultation with AusBiotech members, coupled with technical R&D tax expertise from leading Australian tax experts.

AusBiotech has been a strong advocate for the move to a tax credit since its recommendation by Dr Terry Cutler in the Innovation Review of 2008, as good for the biotechnology sector and for small innovative Australian companies generally.

AusBiotech agrees with Minister Kim Carr, who said the proposed tax credit "...is a great reform in an area where reform is desperately needed." I understand that the accounting community, the biotechnology, medtech and pharmaceutical industries all believe the move to the tax credit is the right government policy, and best for Australian innovation.

While AusBiotech still has a small number of residual concerns (outlined below), we sincerely respect the Minister's intention as announced in the 2009 Federal Budget. We understand some elements of corporate Australia are resisting the legislation, looking for amendments, and we urge the Government to persist with its passage. The majority of issues have been resolved and we need to continue and expedite resolution of any residual issues.

**Comment and key concerns**

Claiming on overseas activities

Biotechnology companies welcomed the news in the first exposure draft that the proposed legislation would allow, with the pre-approval of Innovation Australia, a claim of more than the current 10 percent ceiling. As an industry that is born global and has serious limitations within Australia in the conducting of clinical trials, in terms of accessing specific populations and highly-specific expertise, the change was considered sensible and genuinely supportive of world-class medical research.

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The first exposure draft appeared to give reasonable provisions and give those companies that are required to conduct R&D overseas greater eligibility to claim genuine R&D costs. However the changes that appear in the second exposure draft constitute a significant return to the (unsatisfactory) position of the concession. The new test, whereby overseas activity must incur fewer expenses than related activities in Australia or they are eliminated from eligibility, leaves us concerned that many companies will not be eligible.

Some companies are required to go overseas for toxicology work or for clinical trials that require higher numbers or different patient types, in order to gain FDA approval. These activities are expensive, but necessary R&D activities. The expenditure ought to be considered essential and appropriate for the development of Australian companies and innovation.

#### Practical implementation

Given the entirely new tax credit program and enhanced powers of Innovation Australia (the Board) and AusIndustry, the program will need strong checks and balances. Appropriate training and expertise, and a clear and transparent process are vital to deliver the program consistently.

We have a small amount of evidence from the early implementation of Commercialisation Australia that different officers have different views and therefore give different, at times conflicting, advice - and this can have a negative and unintended impact on the biotechnology companies involved. Sector-specific guidelines, supporting materials, communication and training will be key to a consistent and appropriate delivery of the policy.

AusBiotech offers its support and assistance to Government with the drafting of clear and effective guidelines.

#### Administration of pre-determined claims

The requirement of differentiating core from supporting activities coupled with the inherent uncertainty of this new program in establishing eligibility, suggests that more claimants will take the opportunity to have their eligibility pre-determined or pre-approved by Innovation Australia.

We strongly support the ability to have activities pre-approved, as small and start-up companies cannot afford to get it wrong. We expect this feature of the program will be in demand, especially in the early years of the program.

What measures will be taken to remove unnecessary delay caused by the volume of applications?

#### Feedstock rule

We were very pleased that the Government was responsive to industry-wide feedback and agreed to remove the 'augmented feedstock provision' from the legislation. However, with the new terms mooted to be in line with the provision of the tax concession, but not yet drafted, it is difficult to form a view.

## **Recommendations**

To encourage the biotechnology technology sector to conduct R&D that will benefit Australia and Australians, we recommend the following:

### Claiming on overseas activities

The wording and provision in the legislation to be eligible to claim R&D conducted overseas, should be aligned with that published in the first exposure draft's explanatory memoranda. That is:

The Innovation Australia Board can give approval for an R&D activity to be conducted overseas but only where:

- there are physical limitations on an R&D activity being conducted in Australia;
- the activity to be conducted overseas makes a significant scientific contribution to related R&D activities conducted in Australia; and
- the related R&D activities to be conducted in Australia will be significant relative to the activity to be conducted overseas.

(Page 7 of ED 1 explanatory materials)

### Practical implementation

Appropriate training and expertise, and a clear and transparent process are vital to deliver the program consistently. To assist with clarity, certainty and simplicity, it would be of great benefit to claimants and improve the administration of the concession if industry-specific guidelines and examples were released and updated on a regular basis.

We also recommend that given the unique nature of biotechnology development that industry-specific training be provided to officers who will be responsible for administering and making decisions about claims and giving advice.

We also urge the Government to develop sector-specific guidelines and supporting materials for potential claimants. At present, the dearth of biotechnology-specific examples is impeding understanding of the program.

Conversely the biotechnology sector would appreciate the provision of officers' time to speak at industry information sessions, which AusBiotech plans to host once the program's details are confirmed.

### Administration of pre-determined claims

As we believe the opportunity to have eligibly pre-approved will be enthusiastically taken, we encourage the Government to ensure adequate provision and process for this to occur efficiently.

## Feedstock rule

We anticipate that the feedstock rule's final form will be in-keeping with that used with the tax concession. However, given the final version wording is not yet available, we recommend the Government provide this for comment as soon as is practical.

## **Summary**

With some minor amendments, we believe the Government will be able to achieve its objectives for the new tax credit – that is, implement a more generous, more predictable and less complex incentive that maintains revenue neutrality.

We fully support the Government's persistence in seeking to have the new legislation passed in the time for the commencement of the new financial year.

Cognisant of the unique business model required by biotechnology, where significant funds are required up front before any return can be realised, sympathetic public policy, including tax incentives and access to capital, are vital if innovations and the start-up biotechnology industry are to thrive in Australia. We believe the tax credit is the right tax incentive for Australian innovation.

AusBiotech is available and committed to working with the Government to achieve the intended result of the tax credit. If you would like to discuss this submission, please feel free to contact me on [alavelle@ausbiotech.org](mailto:alavelle@ausbiotech.org) or on 03 9828 1404.

Yours sincerely



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CEO, AusBiotech

*Also refer to AusBiotech's previous submissions on the subject of R&D tax credits; (1) Response to the consultation paper, in October 2009; and (2) Response to the initial exposure draft in February 2010.*