



AusBiotech's pre-Budget submission to the Federal Government

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Introduction

As the Australian representative body of one of the world's most innovative industries, AusBiotech is pleased to submit in advance of the May 2015 Federal Budget.

AusBiotech works to grow Australia's strength in biotechnology and 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 900 biotechnology companies (400 therapeutics and diagnostics and 500 – 900 medical technology companies) and employs in excess of 45,000 Australians.

AusBiotech makes this submission in the belief that biotechnology is a core element of our future, both in social and in economic terms, globally and for Australia. The mapping of the human genome marked the opening up of a whole new world of bioscience and of its potential to underpin innovative and knowledge-based economies and industries. Australia, recently ranked fourth in the world for its biotechnology achievement, has the opportunity to exploit its strength by investing in a sustainable ecosystem – or to waste the momentum it has built.

Value of building a bio-economy

Around the world, along with the trend in all developing and growing countries, the shift from industrialisation to service and knowledge industries is inevitable. For example, the factors of production in the 20th century – land, labour and capital – have been superseded in the 21st century by creative, human and social capital. We live in a time where technological innovation, knowledge and networking are the drivers of our productivity.

The structural shift from the industrial revolution to the knowledge revolution is irreversible and pervasive. The macroeconomic shifts will bring different opportunities in the future and if we can plan appropriately for these, all Australians will benefit. This has greater implications for the Federal Budget each year as the shifts take hold.

The modern world is beset with issues of grave significance – from climate change, cleansing waste streams, food production and quality, alternative fuel developments, through to the ills experienced by ageing populations and increasing incidence of serious infections resistant to antibiotics and increasing prevalence of tragic diseases like Alzheimer's. Australia is not quarantined from these challenges and innovation is the tool by which we can seek redress, solutions and build ourselves a knowledge-based economy.

Individuals alive today are part of an active revolution, which has taken the building blocks of biology and applied them to a wide range of important problems. In the developed world and for many in the developing world, people are touched by or reliant on biotechnologies – just not aware of the term or the revolution it represents. Biotechnology is one of the most innovative industries in the world.

The Reserve Bank of Australia says the structure of the Australia economy is moving from its historical agriculture, mining and industrial base to more of a services base ('Structural Change in the Australian Economy', 2010) and we now prefer to think of ourselves as a smart country, where we compete on a world stage in the knowledge economy. Australia has expertise in all of the area of biotechnology flagged above by the US, which could and should be leveraged to our economy's advantage.

Biotech's capacity to support the economy

Australia has for some years realised the positioning of innovation as central to jobs, productivity and a thriving economy.

In Australia, the economy needs to diversify from mining, car manufacturing and agriculture. While they are or have been essential parts of our economy, we need to understand and build on the key industries of the future; the industries that will employ our educated young people, create wealth and jobs and deliver products and services to a waiting community. Biotechnology not only performs all these functions, but it also assists the mining and agricultural sectors. Biotechnology-based products epitomise advanced manufacturing, an area where we have a comparative global advantage.

Australia already sits in an enviable global position in biotechnology and with the right public policies in place it is poised to provide a significant contribution and underpinning to the Australian economy.

Australian biotechnology innovation ranks fourth on the world stage (Scientific American Worldview 2014). The annual scorecard ranks countries' biotech performance across seven categories: productivity, intellectual property protection, intensity, enterprise support, education/workforce, foundations, and policy and stability. Australia ranked extremely well on the scorecard, jumping from seventh position to fourth. Significantly, the Report's authors noted that if the ranking was based purely on productivity, Australia would jump to second place. Australia joined the top positions across several areas, including:

- Greatest public company revenues (US, UK, Australia);
- Most public companies (US, Australia, Canada);
- Greatest public company market cap (US, Australia, UK);
- Most public company employees (US, Australia, France);
- Best brain gain - share of global graduate students (US, UK, Australia);
- Largest public markets for biotechnology (US, Australia, UK);
- Best growth in biotechnology public markets (US, Australia).

(http://www.scientificamerican.com/wv/assets/2014_SAWorldView.pdf)

Australia's ASX-listed biotechnology companies have a combined market capitalisation of just over \$50 billion for 86 companies (*BioForum*, October 2014), and the sector raised \$458 million in capital investment last year.

Australian biotechnology has global companies, such as CSL, Cochlear and ResMed, which have been responsible for world-leading technologies. Our medical discoveries have improved the quality of health for millions of people across the world, including a role in the development of penicillin, the Cochlear hearing implant and the cervical cancer vaccine (Gardasil).

Australia's comparative advantage comes from its world-class science and medical research, its intellectual property protections, its capacity for international partnerships, and a transparent and high-quality regulatory system. It is also recognised for its capability in Phase 1 clinical trials.

In public policy terms, the 2012 introduction of the Research and Development (R&D) Tax Incentive was a momentous and pivotal inflection point for Australian innovation, which can be traced back to the Cutler Innovation Review recommendations of 2008. We as a technology community already look back in admiration and congratulate the architects of the incentive for their foresight – as it is active in supporting developing local companies and attracting companies from around the world to bring their R&D innovation here.

With our proximity to Asia, Australia's biotechnology industry is poised for growth and well positioned in the global context to contribute to the economy and the lives of Australians, *but* the work on public policy settings is critical.

The problems

Biotechnology companies seeking to commercialise technologies are vulnerable to public policy settings, partly due to their typically small size and lack of retained earnings that usually buffers companies from tough times and partly due to the youth of the innovation ecosystem in which they are seeking to grow.

There are also a range of policies impacting Australia's ability to keep its home-grown technologies in the country and to reap the full benefit they have to offer. Australia does an outstanding job of innovating, especially in the early research phase, only to leave a public policy gap that allows our technologies to leave our shores just as we are able to reap the greatest benefits from them.

Unlike tangible goods, the portability of intellectual property (IP) makes it especially easy to move its management to another jurisdiction and the decision about where to locate the management, manufacture, registration and sale of technology-based products is dictated more so by the business and public policy environment and what it offers.

Australia already supports the R&D phase of innovation in company settings via the R&D Tax Incentive, but support phases out at the commercialisation point of innovation, at which time Australian IP is vulnerable to being sold, managed or manufactured overseas and the resulting community and economic benefits going with it.

The gaps in the ecosystem that are allowing our assets to depart our shores are created by: a lack of venture capital funds in Australia to support commercialisation; and the global competition in tax incentives. These items separately or combined act as magnets from other countries that draw our assets and their potential benefits away from Australia.

When it comes to fundamental discovery in science and biomedical research, Australia is a legitimate and impressive global contributor, producing 3% of the world's research publications with only 0.3% of the population. However, our ability to translate this strength into tests, cures, treatments and vaccines to benefit the Australian community continues to fall short of expectation.

Australia's current reality is that our country spends billions of dollars of public money on world-class research and technology development, only to bid it farewell when the benefits start to really flow.

The solutions

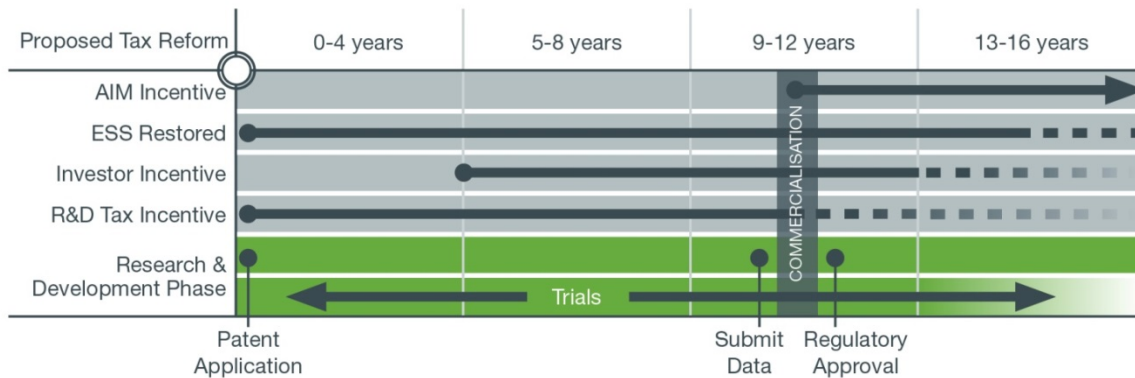
Tax reform

AusBiotech is leading the industry's call for further tax reform in Australia to provide incentives for innovative companies and high-tech manufacturing to support Australia's future and keep us internationally competitive by attracting and retaining business, and the resulting jobs and exports.

AusBiotech advocates making tax incentives an asset for innovation and business, with four pillars:

- Retain the R&D Tax Incentive in-tact, and lift the \$20 million cap for the refundable component to \$50 million in-line with the Cutler recommendations of 2008
- Introduce the Australian Innovation & Manufacturing (AIM) Incentive, to incentivise the monetisation of IP, and in turn innovation, and retain the associated benefits once it reaches commercialisation;

- Introduce fiscal incentives for investors in pre-revenue and start-up companies, to encourage 'patient' venture capital; and
- Restore the Employee Share Scheme (ESS) to its pre-2009 form, at least for start-up companies. (While this was announced in the Industry Innovation and Competitiveness Agenda II&CA in 2014, the draft legislation, which is currently open for consultation, suggests eligibility conditions that are too restrictive to be especially helpful to biotechnology companies.



It's imperative that Australia takes action to remain competitive and relevant on the world stage, especially, when other economies including the UK or Singapore are already reaping the benefits of their tax regimes and some Australian companies are moving operations to these nations to develop IP that originated in Australia. Maximising Australian innovation and reinvigorating the manufacturing sector in Australia largely depends on the existing R&D Tax Incentive being complemented with a tax regime that can secure Australia's competitiveness for the future. As R&D and patent box incentives become more commonplace around the world, a number of governments have demonstrated that to stay competitive, it is necessary to offer a competing tax and business environment. Ten percent of something will be better for Australia than 30% (corporate tax rate) of nothing, which is what we have when companies take their IP elsewhere.

R&D Tax Incentive

The R&D Tax Incentive was very well received by the industry and the annual *Biotechnology Industry Position Survey* shows its in-tact preservation remains the number one public policy issue within the industry year after year.

The R&D Tax Incentive has also had the effect of attracting international businesses to base operations here and in some cases move their operations to Australia. For example, in late 2013 Innate Immunotherapeutics moved from New Zealand to Sydney and has since listed on the ASX, as a result of the R&D Tax Incentive.

When the Cutler Innovation Review of 2008 outlined a vision for the R&D Tax Incentive (then called the R&D Tax Credit), it recommended the cap for the refundable component be placed at \$50 million turnover. The current cap for refunds of \$20 million is achieving its policy intent for very small and pre-revenue companies, but cognisant of the large money values required in technology development, this refinement would assist in the re-targeting of the support toward small companies that are currently excised from the refunds scheme despite their comparative small size.

AIM Incentive

In August 2013, Industry welcomed 'The Coalition's Policy to Boost the Competitiveness of Australian Manufacturing' and its pledge to consider a 'patent box' tax incentive and its recognition that manufacturing is a platform for development of skills and knowledge.

The AIM Incentive would reward innovative Australian businesses that make profits from qualifying patents and make Australian innovation more internationally competitive. Its purpose is to encourage the commercialisation phase of innovation by providing an incentive to locate high-value jobs associated with the development, manufacture and exploitation patents in the country with the incentive. The AIM incentive can also be used to attract overseas IP and associated benefits (such as jobs, skills, manufacturing) to Australia.

While R&D incentives are designed to encourage activities that will result in innovation, the AIM Incentive is aimed at commercial activities, by providing tax relief (10% tax rate instead of 30%) on profit from qualifying patents.

Please see a separate joint submission by AusBiotech, Cook Medical, the Export Council of Australia and the Medical Technology Association of Australia, which sets out the case for the AIM Incentive.

Incentive for investors in pre-revenue and start-up companies

AusBiotech is advocating for greater incentives to encourage investors to provide capital to the life sciences sector. In particular, there is a gap in the various incentives that exist to encourage investors to 'park' their capital in pre-revenue, pre-dividend companies for more than 12 months.

These so-called 'patient investors' are desirable as they provide more stability and certainty to young start-up companies. There are a number of models that may be considered: a Flow Through Share (FTS) scheme, like the mining industry has recently been provided, a preferential capital gains tax scheme or a model like the UK's Enterprise Investment Scheme (EIS).

The EIS is designed to help smaller higher-risk trading companies to raise finance by offering a range of tax reliefs to investors who purchase new shares in those companies.

Employee Share Schemes

The Government is to be commended for its II&CA. In particular the biotechnology industry warmly welcomes improvement to ESS to: reverse some of the changes made in 2009 to the point at which rights issued as part of an employee share scheme are taxed for employees of all corporate tax entities; and to introduce a further tax concession for employees of certain small start-up companies. However, some aspects of the proposal as outlined in the II&CA announcement documents could in practice prevent this policy realising its intent, notably the narrow eligibility.

The 2009 changes to ESS, as predicted, have reduced employee participation and reduced employer offerings. As a result the majority of companies deserted the scheme. Industry's concerns proved to have substance with:

- Over 90% of all plans suspended during the first year, and 30% suspended for up to two years (the majority have not been reinstated); and
- The number of employees participating in, and the amounts they've invested in, employee share ownership plans substantially diminishing since 2009.
- The requirement for valuations of pre-revenue technology companies also provides an unnecessary impost on small business and is arguably meaningless for R&D companies.
- A new report (July 2014) shows that a reversal of the 2009 ESS laws would potentially boost the Australian economy by more than \$1.4 billion in the long term, adding to benefits that would also be derived for small companies to be able to afford the attraction of quality staff and therefore the support for innovation.

The importance of ESS is especially poignant and amplified in the biotechnology sector, where the pre-revenue phase is typically extended by the need to clear regulatory hurdles before revenue can be earned – often by more than a decade – and the cash required to reach regulatory approval.

Start-up companies in this sector are rarely funded by sales revenue, even after listing, and rely on venture capital or share issues to conduct research and development and prepare a product for registration and to earn revenue. In this ‘cash pressed’ state they often rely on the support of ESS to attract quality employees, and are an important support in enabling innovative start-up companies to establish. ESS complements cash remuneration, making a salary package appear more substantive and attractive, in addition to mutual benefit of giving employees a vested interest in the success of the company.

Defining ‘start ups’

The definition of a start-up in the proposed ESS legislation is unhelpful for a number of biotechnology companies. Under the definition in the draft legislation a start-up company means an Australian tax resident employer that offers for acquisition ESS interests in an unlisted company with an aggregated turnover not exceeding AU \$50 million, with having been incorporated for less than 10 years.

The requirement for all three conditions to be met to be an eligible start-up, will exclude many biotechnology companies, notably those who list on the Australian Securities Exchange early in their life cycle to raise capital for their research programs, despite having no or negligible turnover and are yet to make profits. It is often assumed that listed companies are liquid and have ready access to capital. That’s not the case in the biotechnology sector and these companies can remain start-ups in every other sense. Therefore, the exclusion of listed companies actively works against the policy intent.

Further, the condition that the company be under 10 years old is very restrictive for the biotechnology sector, as many start-up companies would not have reached the point of sales revenue by this time. For example, the development of a new therapy can take 15 years before it is approved for the market. Extending this time to 15 years would be more appropriate.

While acknowledging that defining a ‘start-up’ is fraught with issues, for this eligibility definition to fit the intent to support innovation without being too broad, AusBiotech suggests the following as a workable solution.

Use the existing definition (with an extension to 15 years) and also allow for listed companies that meet the eligibility criteria for the refundable R&D Tax Incentive (aggregated turnover under \$20 million) to be included.
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The exemption for start-up companies is critical as it recognises the difficulty innovative start-up companies face in developing their technologies, while retaining highly-skilled workers. It is also critical that it be appropriately targeted. The current definition will inadvertently exclude the type of company it seeks to assist.

A significant practical effect of the tight definition, should the legislation be progressed as proposed, would be to disqualify highly innovative sources of future growth for our economy.

Support for commercialisation

Australia already has a recognised problem in translating our world-class research into cures and treatment, products and services. A number of measures announced in the 2014-15 Federal Budget further removed the little available support for commercialisation and may seriously damage Australia's hard-won momentum in innovation. With the support for commercialisation that was removed in the last Budget (Commercialisation Australia and the Innovation Investment Fund to cease), the level of difficulty in translating research that reaches patients/consumers is even harder than it was.

Also announced in the Budget was the establishment of the Medical Research Future Fund (MRFF), which was welcomed as a great nation-building investment for Australia. AusBiotech has publicly congratulated the Government on creating the initiative and fully supports its implementation. It will make a material difference to Australians' future and will be seen over time as a foundation strategy for improved commercialisation of quality discovery in Australia.

AusBiotech also urges the Government to consider the dedication of a significant portion of the MRFF proceeds, material to achieving the policy intent, to the translation of research, in-line with the *Strategic Review of Health and Medical Research (2013)* (the McKeon Review) recommendations. To do so would give us the best possible opportunity to turn our investment in discovery and ensure it results in gain to the Australian community in terms of needed therapies, tests and devices.

A key element of the report was the strengthening of commercial pathways to ensure the translation of research outcomes into health and economic benefits for the Australian community, and recommends that funding address the twin "'valleys of death' in commercialising research and called for the establishment a Translational Biotech Fund".

Public sector research cannot be successfully commercialised without private investment at some point. In the medical discovery area, the need for capital is high and the pre-revenue phase long. This combination requires an effective and stable collaboration between government and private capital to optimise national benefits.

There is universal support for a fund designed to improve the national success rate for commercialising good science. In order to optimise this policy objective, we believe that the fund should be directed to Australian companies commercialising discoveries in the life science space and that part of the fund principal (10%) ought to be applied.

In terms of financial architecture, we suggest a rolling 'Translational Biotech Fund' providing a consistent and predictable resource for earlier stage life science companies. AusBiotech is of the firm view that the R&D Tax Incentive is effective and has demonstrated success in stimulating faster progress for Australian life science companies. The definition of "R&D" as prescribed by the existing tax legislation ought to be the reference point for determining translational fund eligibility. This approach delivers consistency and simplicity.

Whilst the argument that there are serious financial constraints for early stage life science companies in Australia is correct, it is also true that there remains a dearth of capital throughout the life cycle of companies and this reality should not be overlooked. A balanced approach is best – with private investors collaborating with government at later stages of company development. The

venture capital sector must be involved and with the demise of the International Investment Fund, the MRFF will play an important role.

Clinical trial reform

The Clinical Trials Action Group (CTAG), convened by the Federal Government, made 11 recommendations in 2011, designed to make the process of initiating and conducting clinical trials in Australia significantly more efficient and cost-effective – and therefore help Australia attract a larger global share. The benefits for Australia are not only in the economic activity clinical trials generate, but also in the access for patients to developing treatments, particularly for patients with life-threatening illness.

Unfortunately, nearly three years after the release of the CTAG recommendations, and despite \$9.9 million in allocated funding to complete the work, these recommendations have still not been implemented to the extent necessary to change the realities on the ground. The McKeon Review, noting the lack of progress in 2013 recommended the “acceleration of clinical trial reforms”:

The most important of the CTAG recommended reforms, harmonisation across the states and territories of Australia for clinical trial ethics and governance approvals, has remained elusive.

The McKeon Review recommended the reform be achieved by building on the CTAG report recommendations with the following actions, which AusBiotech supports to drive a national implementation approach to clinical trial reforms:

- Establish 8–10 national ethics committees to replace the proliferation of local committees.
- Implement a national clinical trials liability insurance scheme.
- Create a national clinical trials office within the HMR leadership body to drive reforms.

AusBiotech urges the Government to address this issue if Australia is to retain a healthy clinical trial component to its innovation ecosystem and provide access to therapies for the Australian patient population.

Summary

Australia has excellent potential to be a nation driven by bio-innovation. We have a strong education system, stable government, good regulatory, intellectual property and legal environment and a proven track record in innovation. However, we have unstable public policy supporting innovation, constantly changing programs and a handful of critical gaps.

Critical to our ability to succeed are to retain the benefits (economic and health related) of our world-class medical research are:

- A tax regime to support our international competitiveness;
- Support for commercialisation to ‘bridge’ the gaps and ensure our discoveries become the real solutions and treatments they promise to be; and
- Clinical trial harmonisation.

If we as a nation are serious about innovation, we must address the gaps and leaks, as outlined in this submission, to create the right environment for innovation to thrive – and the coming Budget provides a not-to-be-missed opportunity.