

**Submission to the Federal Government's  
National Innovation System Review**

**Dr Anna Lavelle**  
**AusBiotech**  
30 April 2008

AusBiotech Ltd  
ABN 87 006 509 726  
Level 1, 322 Glenferrie Road  
Malvern Vic 3144 Australia  
Telephone: (03) 9828 1400  
Fax: (03) 9824 5188  
Email: [admin@ausbiotech.org](mailto:admin@ausbiotech.org)  
Website: [www.ausbiotech.org](http://www.ausbiotech.org)

Introduction .....	3
Executive Summary .....	5
1. Government policy .....	14
1.1. National Innovation Priorities .....	14
1.2. Engagement with Asia-Pacific .....	14
1.3. Procurement .....	15
1.4. Leadership .....	16
1.5. National coordinating biotechnology agency .....	16
1.6. Whole-of Government approach .....	17
1.7. Commercial Ready .....	17
1.8. Tax .....	19
1.9. Bioinformatics .....	22
2. Public good .....	23
2.1. Publicly Funded Research Organisations .....	23
2.2. Environment .....	24
2.3. Agriculture .....	25
2.4. Small business .....	25
3. People, Culture, Education .....	26
4. Linkages and Clusters .....	28
5. Domestic and International Customers .....	29
5.1. Identifying and meeting the needs of customers ....	29
5.2. Clinical trials .....	30

## Introduction

AusBiotech is the national industry organisation that represents one of the key industries of the future: biotechnology.

It is through a properly supported biotechnology industry that we will see solutions emerge to confronting global issues – whether they are in health, climate change, food or fuel. Biotechnology will be the 'enabler' to assist achievement of breakthroughs and drive wealth creation in Australia.

AusBiotech represents an industry that is the sixth largest of its kind in the world<sup>1</sup>. The organisation is the third largest biotechnology industry organisation in the world and runs the most successful international annual conference in the Asia-Pacific region.

AusBiotech represents 3000 members covering the human health, agricultural, medical device, environmental and industrial sectors in biotechnology. AusBiotech is dedicated to the development, expansion and prosperity of the Australian biotechnology industry by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

We echo the Chair of the Review Panel, Dr Terry Cutler, when he points out in the Call for Submissions, "standing still means going backwards."

This submission from AusBiotech has identified key priority areas and sourced fresh ideas for improving the efficiency and coherency of Australia's National Innovation System, particularly in the area of biotechnology, for the decades ahead.

To compile this submission, AusBiotech sought a comprehensive range of views from its members, including senior executives from large and

---

<sup>1</sup> Beyond Borders - Ernst & Young Global Biotechnology Report 2007

small companies; as well as its Board of directors and staff. AusBiotech held a series of CEO luncheons discussing specific tax issues and also ran a half-day workshop, facilitated by Professor Göran Roos of VTT Technical Research Centre of Finland. The outcomes of these discussions are reflected in the recommendations.

AusBiotech has also contributed to the Pharmaceutical Industry Council submission along with the other two council members, Medicines Australia and the Generics Medicines Industry Association. This submission can be found at <http://www.pharmacouncil.com.au>

## Executive Summary

AusBiotech's recommendations to the Review of the National Innovation System are as follows:

### 1. Government Policy

#### 1.1. National Innovation Priorities

##### **1.1.1. Recommendation:**

Establish a national innovation strategy with key prioritised areas. These areas should be expressed in user (benefit) language. Priority areas should receive the full benefits of the public support structure for innovation.

##### **1.1.2. Recommendation:**

Biotechnology and related areas should be a key national priority of the Government as part of the National Innovation Strategy.

#### 1.2. Engagement with Asia-Pacific

##### **1.2.1. Recommendation:**

Promote programs that will build Australian biotechnology and medical device capabilities in the Asian region.

#### 1.3. Procurement

##### **1.3.1. Recommendation:**

Review and clarify public procurement policies to ensure they are designed to gain maximum benefit and support local innovation.

## **1.4. Leadership**

### **1.4.1. Recommendation:**

Utilise leadership at a Cabinet level to ensure Australia's innovation opportunities and capabilities are fully understood, expanded and applied across government.

## **1.5. National Coordinating Biotechnology Agency**

### **1.5.1. Recommendation:**

A central agency overseeing all aspects of biotechnology at the federal government level must be strengthened in a "joined-up government approach" in order to align departmental initiatives and minimise transaction and coordination costs.

## **1.6. Whole-of-Government Approach**

### **1.6.1. Recommendation:**

Senior departmental advisers, with expertise in innovation, from the Department of Innovation, Industry, Science and Research should be seconded out to each relevant department to work with different policy areas to identify future innovation solutions.

## **1.7. Commercial Ready**

### **1.7.1. Recommendation:**

Retain the Commercial Ready Program as the preferred form of government support for many biotechnology and medical device innovations.

### **1.7.2. Recommendation:**

Extend the current funding timeframes for the Commercial Ready scheme to appropriately reflect the longer time to market experienced by biotechnology companies.

- 1.7.3. Recommendation:**  
Expand the Commercial Ready grant amount to increase the matching co-investment and support projects of increased size and complexity.
- 1.7.4. Recommendation:**  
Retain the Commercial Ready Plus program as a highly successful and cost-effective means to determine proof of concept.
- 1.7.5. Recommendation:**  
Establish a process to determine a company's 'proof-of-value' once proof-of-concept has been established.

## **1.8. Tax**

- 1.8.1. Recommendation:**  
Retain both the 125 per cent and the 175 per cent tax concession as an attractive incentive for revenue-positive companies within the biotechnology industry.
- 1.8.2. Recommendation:**  
The current cap on the R&D tax offset must be raised from \$1 million to \$2 million with annual indexation to keep pace with CPI increases.
- 1.8.3. Recommendation:**  
Allow companies to still receive the benefit of the offset if they spend above \$1 million.
- 1.8.4. Recommendation:**  
Further investigate Australia's international competitiveness against other countries (such as the UK R&D tax relief and NZ R&D tax credit regimes) and consider increasing the base concession to 150 per cent.

- 1.8.5. Recommendation:**  
Consider introducing overseas expenditure and patent costs as eligible expenditures for the purposes of the R&D tax concession.
- 1.8.6. Recommendation:**  
Investigate “incentive” programs for larger traditional industry companies to invest in biotechnological alternatives or solutions to their current and future industry needs.
- 1.8.7. Recommendation:**  
Treasury should review the Continuity of Ownership Test and the Same Business Test in light of the unique circumstances of the biotechnology industry.
- 1.8.8. Recommendation:**  
Introduce a regime to turn a fraction of the losses into useable cash, rather than uncertain tax benefits in the future.
- 1.8.9. Recommendation:**  
Introduce a ‘flow-through shares’ scheme, as earmarked for use in the mining industry, as an option for biotechnology companies.
- 1.8.10. Recommendation:**  
Investigate the feasibility of ‘patient capital’, for example reducing the rate of Capital Gains Tax the longer investments are held, to encourage stable investment in biotechnology and small medical device companies.

## **1.9. Bioinformatics**

- 1.9.1. Recommendation:**  
Establish and ensure the sustainability of a national bioinformatics facility with focused infrastructure, advanced R&D, technical training and high-end service

provision roles, as is the case for our major trading partners (US, Europe, China, Japan).

## **2. Public good**

### **2.1. Publicly Funded Research Organisations**

#### **2.1.1. *Recommendation:***

Recruit top management competencies, for example from Europe, that have experience in turning around publicly-funded research organisations such as CSIRO.

#### **2.1.2. *Recommendation:***

Investigate matching funding programs between publicly-funded research organisations (PROs) and companies within prioritised national innovation areas.

#### **2.1.3. *Recommendation:***

Expand the use of public procurement to ensure stimulation of Australian innovation to achieve maximum returns on public funds for the public good – for example in health care, defence, education etc.

### **2.2. Environment**

#### **2.2.1. *Recommendation:***

Invest in the environment as a national innovation priority to encourage biotechnology solutions to the effects of major environmental problems such as fuel shortages, climate change, waste handling, recycling and drought.

#### **2.2.2. *Recommendation:***

Investigate incentives for biotechnology innovation that benefits the environment, for example the use of biological processes to manage waste streams.

#### **2.2.3. *Recommendation:***

Develop a national biological resource centre that sequences Australian biodiversity and allows access on a fee or licensing basis.

**2.2.4. Recommendation:**

Establish a framework to enable industry to provide a benefit from responsible use of Australian biodiversity by providing career incentives for taxonomists.

**2.2.5. Recommendation:**

Streamline legislation across jurisdictions to remove inconsistencies in areas such as state government legislation on bioprospecting.

## **2.3. Agriculture**

**2.3.1. Recommendation:**

Work with the States to remove regulatory confusion and duplication around genetically modified organisms for agricultural applications.

**2.3.2. Recommendation:**

Harness and streamline Australia's agribio research by forming a direct link between industry, the customer and public research facilities.

## **2.4. Small Business**

**2.4.1. Recommendation:**

In conjunction with the Industry Association, develop a mentoring program to provide leadership and advice for small biotechnology/medical device businesses.

**2.4.2. Recommendation:**

Ease the administrative burden on small biotechnology companies for grant applications by developing efficient processes and a positive assistance culture within all government agencies.

### **3. People, Culture, Education**

#### **3.1. Recommendation:**

Work with the Department of Education, Employment and Workplace Relations and State Governments to develop programs to better equip teachers at primary and secondary level with both science skills and the skills to teach science.

#### **3.2. Recommendation:**

Work with the Department of Education, Employment and Workplace Relations and State Governments to develop programs to increase awareness of science-based careers and encourage more students to study science.

#### **3.3. Recommendation:**

Develop a coordinated program in conjunction with participating university departments to capture visiting professors as guest lecturers and guest researchers.

#### **3.4. Recommendation:**

Establish a program to allow researchers to engage in commercial sabbaticals that have political, commercial and research elements to ensure they have a broader base of experience to draw on when entering the private sector.

#### **3.5. Recommendation:**

Better engage and link in with Australia's large diaspora, leveraging their gatekeeping positions abroad to benefit Australian biotechnology industry, and, where possible, find opportunities to bring them home.

#### **3.6. Recommendation:**

Develop a marketing and promotional program between government and industry to promote Australia as a destination for foreign talent in innovation.

#### **3.7. Recommendation:**

Develop an Innovation Internship Scheme to assist biotechnology start-up companies to employ young graduates

and give students a breadth of company experience before formally entering the private sector.

#### **4. Linkages and Clusters**

##### **4.1. *Recommendation:***

Bolster existing biotechnology and innovation clusters with the support and presence of State and Federal Government bodies in the form of co-located procurement offices, ensuring the presence of a potential large customer.

#### **5. Domestic and International customers**

##### **5.1. Identifying and meeting the needs of Customers**

###### **5.1.1. *Recommendation:***

Source human resources from publicly-funded research organisations (PROs) abroad that have already established capabilities in desired markets. Investigate the possibility of subsidising the establishment of international PRO branch offices at suitable locations (within key clusters) in Australia to enhance cluster growth.

###### **5.1.2. *Recommendation:***

Examine the business model managing commercialisation in our universities to improve the balance between the costs of operations (such as staff), the number of patents, ideas, and available funding for investing.

###### **5.1.3. *Recommendation:***

Use already established national resources to support Australian biotechnology companies and SMEs to combat the problem of Australia's distance from global markets and supply chains.

**5.1.4. Recommendation:**

Clarify and specify the role of the Government's newly-established Global Opportunities Division and Austrade with regards to the support of biotechnology and medical device SMEs.

**5.2. Clinical Trials**

**5.2.1. Recommendation:**

Develop a marketing strategy to position Australia as a convenient and expedient service centre of excellence for global clinical trials. Align this marketing strategy with a cluster development strategy for this area.

**5.2.2. Recommendation:**

Streamline the complex regulatory and clinical trial requirements to retain and improve Australia's status as a number one destination for clinical trials for global companies.

## 1. Government policy

### 1.1. National Innovation Priorities

Like any country, Australia has its capabilities, limitations, strengths, opportunities and weaknesses. It makes sense to exploit our natural advantages and aim to excel in these areas.

To this end, the Government's first priority in overhauling the National Innovation System should be to **establish a National Innovation Strategy with key prioritised areas. These areas should be expressed in user (benefit) language and should receive the benefits of the public support structure** whereas the non-prioritised areas should not.

**Biotechnology and related areas should form one of the key priorities of the Government as part of the National Innovation Strategy.** Biotechnology is fundamental to pressing community challenges such as health, climate change, food and fuel supply.

### 1.2. Engagement with Asia-Pacific

Australia's geography and niche capabilities in biotechnology have positioned our industry well in the Asia-Pacific region. Several countries in the region are investing heavily in biotechnology infrastructure, science and manufacturing. Australia needs to be part of a network of nations which will benefit all partners. The Federal Government has a unique opportunity to influence the future of biotechnology in the Asia-Pacific region. It also has an intergenerational responsibility to support innovation which will help Australia determine its own destiny and ensure the growth and premier positioning of Australia in the global biotechnology market. Australia needs to leverage its capabilities and work with other nations in the Asia-Pacific region who have complimentary assets.

In this context, AusBiotech has established and is the secretariat and chair of BioNet Asia Pacific, a network of the industry associations from

10 Asia-Pacific. BioNet Asia Pacific was initially supported by the Federal Government and it is fundamental that support of such initiatives be strengthened. This is a rapidly developing market with available capital. The Government must **promote programs to build on the opportunities for Australian biotechnology in the Asia-Pacific region.**

### 1.3. Procurement

Strong general management and specific public procurement skills are essential for successful public procurement of innovations.

Intellectual property rights problems remain a concern to some of the major suppliers to government and may stop others from seeking to become suppliers. The ownership of intellectual property rights should not always be assigned to the buyer and should ultimately rest with the party who is best able to exploit it.

A common criticism of innovation and procurement is that public customers usually still favour solutions offering the lowest up-front cost. Purchasing on the basis of value rather than cost requires a major shift in emphasis but training and incentive structures that encourage innovative thinking can help to institute change.

Internationally, European Union nations lead the way in using public procurement to spur innovation primarily because innovation is a high-level policy objective. Sweden in particular offers many examples of innovative procurement collaboration occurring through the interaction between public agencies and private firms. The UK Government offers the most guidance on using public procurement for innovation policy purposes.

Specific procurement policies that are properly aligned with strategic priorities (see recommendation 1.1.1) will provide certainty in these priority areas. It is important that **Government review and clarify its public procurement policies and the impact on innovation.**

#### 1.4. Leadership

AusBiotech believes leadership is crucial from the top echelons of government if innovative sectors such as biotechnology and medical devices are to grow and prosper. In Australia we have seen some strong examples of successful political leadership in innovation, which has led to distinct improvements in the sector.

AusBiotech has been encouraged by comments from the Prime Minister, Kevin Rudd, such as:

*"An industry policy is not about whacking up a tariff wall. That debate's been had and it's gone. What I'm concerned about is what you can do elsewhere by innovation policy, research and development, and other things, practical things, in industry policy, which make it easier for this country to have a knowledge-based industry future, and I believe we can do it."*<sup>2</sup>

AusBiotech is pleased that early indications on innovation leadership from the Federal Government have been positive.

**Leadership at a Cabinet level is critical to ensuring Australia's innovation opportunities and capabilities are fully understood, expanded and applied across government.**

#### 1.5. National coordinating biotechnology agency

Biotechnology has a range of important applications that can impact on almost all government departments. Therefore the role of a coordinating agency across government specifically focused on biotechnology is absolutely necessary. To date, Biotechnology Australia has been the body to fill the central government coordination role.

---

<sup>2</sup> 'Industry Revolution' by Shaun Carney, The Age, 12 April 2008

However **the national coordinating biotechnology agency should be strengthened to give it decision-making responsibilities, its own budget and dedicated, senior staff.** As well as providing a coherent policy framework across government, this would also ensure that government funding programs are channeled appropriately through to the industry.

## 1.6. Whole-of Government approach

It is imperative for the Federal Government to lead a coordinated approach and existing mechanisms. One example is the successful Committee for Marketing Australian Biotechnology (CMAB), which needs to be strengthened. Marketing a "*One Australia*" brand and attaining critical mass via national coordination is essential to achieve a strong global presence.

AusBiotech believes greater emphasis would be placed on innovation across government if **senior departmental advisers, with expertise in innovation, from the Department of Innovation, Industry, Science and Research were seconded out to relevant government departments.** The advisers would work in various policy areas to identify future innovation solutions that would be linked to industry and aligned with the National Innovation Priority areas (see recommendation 1.1.1).

## 1.7. Commercial Ready

AusBiotech strongly supports matching funding programs to assist the biotechnology industry. Of the three main avenues of government funding – tax, grants and matching, the latter has the highest beneficial outcome because all parties have aligned interests. Matching funds need to be specifically targeted and linked to areas of priority.

One in three dollars allocated from the Commercial Ready program goes to biotechnology companies. **AusBiotech strongly believes the Commercial Ready program should be retained** as it is a major and important funding source for biotechnology companies. Any

reduction in this program would lead to a reduction in available funding for biotechnology companies. AusBiotech notes that the Commercial Ready program has already been reduced from its original size and further reduction would be most harmful to the industry.

However, there is scope to improve the program's benefits for biotechnology companies. Grants under the Commercial Ready program are generally allocated for three years, which has the unintended effect of punishing success. This is because of a problem unique to the biotechnology industry relating to the extended time it takes to get to market – which can be up to 15 years. Companies who are at the stage of getting traction often find their government support is removed. **The Commercial Ready program should appropriately reflect the real time to market experienced by biotechnology companies.**

Further, consideration also needs to be given to the amount of funding available for each grant application. Currently, this is capped at \$5 million, with the average grant funding being near \$1 million over three years. This limitation can set an expectation with both the project proponent and the investor of the matching funds that Australia has projects of only \$2-3 million. Projects of this size often fail to get the follow-on investment required to take projects and products to the world market. To address this, **the Commercial Ready grant amount should be expanded to increase the matching co-investment, support projects of increased size and complexity and send a clear signal that Australia strongly values its innovation base.**

Further, AusBiotech understands that 30 to 40 per cent of applications to the Commercial Ready Plus program are from the biotechnology sector. This has been an extremely cost-effective and successful way to determine proof-of-concept, which is essential prior to commencing commercialisation. In the past this has been an underfunded area leading to delays and confusion at the proof-of-concept stage. **The Commercial Ready Plus program addresses these issues and must be retained** alongside the Commercial Ready program.

**The Government should consider establishing a process to determine the 'proof-of-value' once proof-of-concept has been established** as has been done by other innovation-focused countries. The process could involve a small committee of experts who determine whether they believe a discovery is commercialisable. To achieve this, the expert committee would require a small fund to seek views from, for example, health economists. This process would strengthen the transition from discovery to commercialisation.

## 1.8. Tax

Biotechnology companies face structuring and funding issues at each stage of their life cycle. The main source of funding for Australian biotechnology companies is IPO but in many cases this is occurring too soon in the life cycle of the company. There are also ongoing operational issues such as the satisfaction of the Continuity of Ownership Test (COT) and Same Business Test (SBT) as they relate to the utilisation of tax losses by a company (ie tax losses incurred become difficult to recoup if there have been ownership and business changes).

AusBiotech argues that biotechnology companies need to be given appropriate consideration for their unique market situation. There are a number of avenues in which the Federal Government could assist biotechnology companies at different stages of the life cycle.

It is a welcome fact that Australia is one of the few countries to offer R&D tax concessions. However to benefit from the tax concession, a business must be a trading company and revenue-positive. Given that for a large period of their life cycle most biotechnology companies are not revenue-positive, they are never able to benefit from the R&D tax concession. **AusBiotech believes that both the 125 per cent and the 175 per cent tax concessions must be retained** as they are an effective incentive for larger biotechnology, medical device and pharmaceutical companies. However it is important to note that the tax concession is of no use to the majority of biotechnology companies, which are small businesses that are not revenue positive.

Separate measures such as the Commercial Ready program (see recommendation 1.7.1) need to be available for this market sector.

Furthermore, **the current cap on the R&D tax offset must be raised from \$1 million to \$2 million with annual indexation or regular review to keep pace with CPI increases.** Since the \$1 million cap was set in 1998-99, there has been no indexation. The real net benefit in 1998-99 was 20 per cent. The real net benefit is now closer to 7 per cent.

**Companies must also be able to still receive the benefit of the 125 per cent tax offset if they spend above \$1 million.** Currently companies who spend anything over \$1 million on R&D are unfairly punished as any tax benefit is cut out. Companies spending over this arbitrary amount should not lose the benefits of the offset regardless of their spend.

In order to remain internationally competitive in today's dynamic market, AusBiotech also recommends that Government leverages from international examples (for example the UK, Singapore and NZ) where they have increased their tax concessions and reliefs to attract R&D innovation; and **consider increasing Australia's base concession to 150 per cent.**

AusBiotech believes that the long term sustainability of the Australian economy is closely tied with the creation of Intellectual Property (IP) in Australia. In order for Australian companies to be internationally competitive, we need to encourage companies to have "best practice" methodologies. Best practice involves international specialisation of activities. Where overseas expenditures are incurred by Australian companies to develop Australian IP, **AusBiotech recommends that overseas expenditure should be eligible for full the R&D tax concession** and not subject to certain requirements under section 39ED of the Industry Research and Development Act 1986 (for example the 10 per cent limit). Furthermore, in order to encourage IP retention and management in Australia, **AusBiotech believes that IP costs (registration, renewal, infringement and defence) should also be eligible for the R&D tax concession.**

There should also be an investigation into possible **“incentive” programs for larger traditional industry companies to invest in biotechnological alternatives or solutions to their current and future industry needs.**

Biotechnology companies find it virtually impossible to take advantage of accumulated tax losses. Because of their unique industry characteristics, it is extremely difficult for biotechnology companies to meet the two tests prescribed by the income tax legislation, namely:

- Continuity of ownership (COT) - more than 50 per cent of ultimate ownership has to be the same (as tested at different stages during the period between the year the loss is incurred and the end of the year in which a loss is sought to be utilised)
- Same Business Test – where the COT is failed, entities may continue to utilise tax losses carried forward if the SBT is satisfied. Broadly, there are three aspects of the SBT that must be met in order for a company to be able to utilise its tax losses:
  1. the company must carry on the same business for the whole income year of recoupment as it carried on immediately before the relevant change in ownership (the change-over);
  2. the company must not derive assessable income from a business of a kind which it did not carry on before the change-over; and
  3. the company must not derive assessable income from transactions which are outside the course of the business operations carried on before the change-over.

An inability to meet these tests means that unlike other companies, biotechnology companies cannot ascribe value to the accumulated losses if involved in a merger or acquisition. This devalues biotechnology companies engaging in M&A and capital raising and may act as a disincentive for potential new investors being introduced.

**Treasury should review these two tests in light of the unique circumstances of the biotechnology industry.**

**Policies could also be considered to turn losses into useable cash, rather than uncertain tax benefits in the future. One option is a refund of certain amounts of cents per dollar value of losses** – even if this is only a small figure (for example 3 cents in the dollar), the certainty and immediacy of this benefit may be of more value than uncertain recoupment in future. The additional cash arising from such a scheme could be used to fund further research and development etc. However such a scheme would require careful consideration and we would welcome the opportunity to consult on the details of such a policy.

The Government could also **introduce a 'flow-through shares' scheme**, as earmarked for use in the mining industry, as an option for biotechnology companies. Such instruments are currently used to positive effect in Canada.

Recently modified venture capital concessions are not being used in the biotechnology industry as much as anticipated. **'Patient capital', as used in the US and UK for some shareholdings, where the rate of CGT is reduced the longer interests are held, would be of particular benefit to start-up companies.** A 50 per cent discount on capital assets held over 12 months by individuals already exists, but a similar concession is not currently available for companies. This would provide some incentive for investors to get in and stay in, and would perhaps reduce 'speculative' or 'year end' investments.

## 1.9. Bioinformatics

Since the advent of genomics, biotechnology is increasingly based on advanced information and communication technology (ICT) for the management and analysis of large-scale biomolecular data. Bioinformatics is the interface between bioscience and ICT, and directly enables innovation across industrial, agricultural, biomedical and environmental biotechnology. Genomic bioinformatics is a highly specialised, large-scale undertaking that requires focused, sustained investment in infrastructure, advanced R&D, technical training and outreach to the commercial sector both qualitatively and quantitatively

different from current programs in funding agencies and individual NCRIS (National Collaborative Research Infrastructure Strategy) capability areas. **Consideration should be given to establishment of a national bioinformatics data and infrastructure facility** with broad mandate within the innovation system.

## 2. Public good

### 2.1. Publicly Funded Research Organisations

Investments in public good – our health system, environment, defence – are mainly the Federal Government's domain. Biotechnology has a significant opportunity to both contribute to and benefit from these public good investments because of its potential to solve key problems in areas such as health, the environment and defence.

AusBiotech believes the most valuable contribution of publicly-funded research organisations (PROs) is through basic research. CSIRO, as Australia's major publicly-funded research organisation, is increasingly being driven by commercially focused KPIs, which lead them beyond the research phase and into the development phase of the life cycle. This often leads to a situation where CSIRO and biotechnology companies compete. CSIRO's performance as it relates to primary stakeholders in the biotechnology sector needs to be improved.

International experience shows the best PRO models are applied research institutions. Australia should **recruit new top management competencies, for example from Europe, that have experience in turning around publicly-funded research organisations.**

The idea of **matching funding programs between publicly-funded research organisations (PROs) and companies within prioritised national innovation areas** ought to be investigated.

**The use of public procurement should also be expanded,** particularly in key cluster areas (see recommendation 4.1), to ensure stimulation of Australian innovation to achieve maximum returns on

public funds for the public good – for example in health care, defence, education etc.

## 2.2. Environment

Australia faces enormous challenges in terms of its management of the environment – including managing biological resources, water shortages, environmental degradation, alternative energies and climate change. These are challenges which also have significance on a global scale.

**The Federal Government should invest in the environment as a national innovation priority** to encourage biotechnology solutions to these problems.

There is great potential for innovation, and in particular biotechnology, to play a role in solving key environmental problems in Australia.

**Incentives could be developed for the use of biological processes to manage waste streams.**

Australia has 10 per cent of the world's biota, presenting significant opportunities to screen for novel molecules that may have diagnostic, therapeutic or industrial uses. **A national biological resource centre that sequences Australian biodiversity and allows access on a fee or licensing basis could be developed.**

Furthermore, Australia needs a framework to enable industry to provide a benefit from responsible use of Australian biodiversity and part of that framework could be **to provide career incentives for taxonomists.**

There should also be an effort to **streamline legislation across jurisdictions as there are many inconsistencies, such as the varying state government legislation on bioprospecting.**

## 2.3. Agriculture

There is a 12-20 per cent return <sup>3</sup> on the investment of agriculture R&D activities as a matter of public good. Adaptation of crops; development of renewable fuels using second and third generation technologies; sourcing novel biomaterials to replace petroleum sourced plastics; and improving nutritional composition are some of the areas where Australia can benefit.

The current regulatory environment where genetically modified crops can be approved by the Office of the Gene Technology Regulator and Food Standards Australia New Zealand but stopped at the State level creates uncertainty. Coordination by the Federal Government and cooperation from the States is required to **remove regulatory confusion and duplication in legislation on genetically modified organisms for agricultural applications.**

Finally, there is a need to **harness and streamline Australia's agribio research by forming a direct link between industry, the intended customer and public research facilities.**

## 2.4. Small business

With almost two million in Australia, the small business sector is often referred to as the backbone of our country. Within the biotechnology and medical device industries small business is even more highly represented, with around 80 per cent of the 1100 biotechnology and medical devices companies employing fewer than 20 employees.

Small businesses in biotechnology and medical devices need assistance if they are to grow and innovate. The majority of small business people in the biotechnology and medical device industries are not lacking in technical or scientific skills. Rather, their needs are mentoring services and training in basic business skills, as well as

---

<sup>3</sup> Cox, T., Mullen, J. and W. Hu (1997). "Nonparametric measures of the impact of public research expenditures on Australian broadacre agriculture" *Australian Journal of Agricultural and Resource Economics*, Vol 41, pp 333-360.

contact with industry colleagues through networking. Small businesses face barriers in their interface with public/private institutions for one or more of the following reasons:

- They are time-poor
- They lack funds and resources
- They do not always have a suitable competence interface (limited absorptive capacity)
- They face regulatory barriers
- They can lack the skills and knowledge to access global supply chains.

Mentors are of great benefit to small businesses – there is real merit in harnessing the experiences of those who have been down the same track. **AusBiotech would welcome the opportunity to work with the Federal Government to develop a mentoring program for small biotechnology/medical device businesses**, allowing them to see different aspects of the path to success.

**Paperwork is an enormous burden on small business and should be reduced by developing more efficient processes.** For example, when a company expresses an interest in applying for a grant, a process should be triggered within the department that does not overly burden the small business.

### **3. People, Culture, Education**

This section looks at Australia's attitudes and values towards biotechnology and innovation. Do we value entrepreneurship and creativity? How do we increase this in our community so that we can encourage our students to pursue science in school and contribute to the science based industries after school?

Skill shortages in the area of biotechnology will become a growing problem if it is not addressed now – and at every level of our school system. There appears to be a lack of interest or attractiveness in studying science in school and few accessible success stories and mentors to lead by example. On the business side, scientists often

don't have the business skills to make their companies a success. This can be addressed through our education system. Industry needs to be able to directly influence education outcomes.

To address the skills shortages of the future, we need leadership and inspiration now. Success stories in the innovation world – particularly hard-won successes – are not celebrated enough. Australians are highly innovative and there is much to be gained by placing value on our achievements in innovation and entrepreneurship. In Australian culture sporting figures are worshipped. We should learn how to embrace and place greater value on our entrepreneurs.

Achieving an outcome where more students take up science subjects and pursue a career in science and technology starts with **education of our teachers**. From primary level onward, more emphasis should be placed on 'teaching the teachers' better science skills so that they are enthused and equipped with the knowledge to educate and inspire new generations of students. This is a powerful way to impact on a young person's decision to choose science as a study.

Individual participation should be encouraged and enhanced through a **coordinated, targeted program in our educational institutions to capture visiting professors as guest lecturers and guest researchers**. These visiting professors should come from industry to bring their important perspectives to the students.

**A formal program for commercial sabbaticals**, involving research, political and commercial legs, would allow our up-and-coming entrepreneurs to move around, observe and experience different elements of their industry to give them a more effective, broad-based experience before they head into the private sector.

**Australia's large diaspora is an untapped resource that could be better utilised**. As well as targeting our best and brightest for key positions in our country, we should use the talents of our successful expatriates where they are. Much can be learned from other countries here – for example, the behavior of the Chinese diaspora.

**Further, a marketing and promotional program between government and industry could promote Australia as a destination for foreign talent.**

Faced with scarce resources, small biotechnology companies can be reluctant to employ graduates in spite of the skills the graduate could bring to the business. The Government should examine the establishment of an **Innovation Internship Scheme** to assist biotechnology start-up companies to employ graduates. The scheme could also involve a structured traineeship program where students could have 'hands on' experience, for example, for one day a week as part of their studies. Students could be introduced to a broad range of biotechnology careers through a rotation program over the course of the study, for example one year in a start-up or small company; one year in a large company; and one year in a research centre.

#### **4. Linkages and Clusters**

Cluster networks have worked well in Australia and have an invaluable function in biotechnology. Surprising benefits can be derived when small biotechnology firms are clustered around a multi-national company, investors and research organisations.

In biotechnology clusters, physical location of clusters is the key. Players should be co-located where the customer is. If the customer is Government, then Government should consider co-locating within this cluster.

A good example of a government-driven and supported cluster is the Federal Government's NCRIS program (National Collaborative Research Infrastructure Strategy). NCRIS recognises that national collaboration which delivers needed infrastructure without wasteful duplication is necessary and possible in Australia. AusBiotech is pleased to be project managing the NCRIS funded biotechnology projects and supports the establishment of an approach which delivers university, industry, federal and state government cooperation.

There are numerous examples of successful clusters in areas such as human health and medical devices, which could be **bolstered with State and Federal Government support in the form of a procurement office for products and services** where there is the potential to attract a large customer.

Physically integrating government procurement with business and other organisations would lead to better business outcomes, particularly in terms of export potential as well as enhancing the competence of the procurement organisation.

## **5. Domestic and International Customers**

### **5.1. Identifying and meeting the needs of customers**

One of the elements to achieving success in the biotechnology industry is a matter of finding out who the customer is and what they want to buy. In our global environment, customers can easily be in a different state or a different country. Policies need to be geared towards key markets.

Often a local market is identified but the capability for getting the product to market does not exist. This may happen for example if a national innovation priority is established in an emerging area of biotechnology for which there is little existing infrastructure.

A solution is **to source human resources from publicly funded research organisations (PROs) abroad that have already built in capabilities in the desired area, with the aim of bringing these resources to Australia.** The international PRO would be paid a fixed cost to locate in Australia to provide a dominant market position in one of our priority areas (within key clusters). This is a model that has been used successfully relating to manufacturing competence with the Fraunhofer-Gesellschaft in South Australia.

To properly align industry with the needs of domestic and international customers it is important to **examine the current business model managing commercialisation in our universities**. This would draw down costs and improve efficiency. The present model seems to reflect an imbalance between the costs of operations (such as staff) and the number of patents, ideas, and available funding for investing.

Given Australia's distance from important global markets and supply chains, it is imperative that **the Government uses already established national resources to support Australian biotechnology companies and SMEs to ensure success**.

There is also a need for innovative companies (such as biotechnology companies) to access export assistance. As such, **the role of the Global Opportunities Division and Austrade need to be clarified and those bodies given a specific remit with regard to support of SMEs in biotechnology and the medical device sectors**.

## 5.2. Clinical trials

Clinical trials should be examined as a potential National Innovation Priority (see recommendation 1.1.1). Australia has sound expertise, a rigorous ethical approach and a well-resourced public health system (by world standards). We have an opportunity to take advantage of our expertise in clinical trials and become a world leader in clinical trial services. This innovative approach would also have the benefit of giving Australians first access to new health treatments.

**An aggressive marketing strategy (perhaps using CMAB) should be developed to position Australia as a convenient and expedient service centre for clinical trials**. Matching funds could be offered to companies, hospitals and institutions to achieve this. This could also form the basis for a successful new service cluster.

For this to be successful, **complex regulatory and clinical trial requirements must be streamlined**.