

BSDP Steering Committee  
c/- Skills & Public Support Working Group Chair  
Mr Ken Windle  
Chairman, Advent Pharmaceuticals  
1 Dalmore Drive  
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29 September 2008

Dr Terry Cutler, Chair  
Review of the National Innovation System  
Department of Innovation, Industry, Science and Research  
GPO Box 9839  
CANBERRA ACT 2601

Dear Dr Cutler,

On behalf of the Biotechnology Strategic Development Plan (BSDP) Steering Committee, we commend you and your committee on the release of the Cutler Report covering the Review of the National Innovation System.

The following comments are from the Victorian BSDP Steering Committee, a unique grouping of experts from the public and private sector together with the leading industry Associations. The BSDP Steering Committee was established as part of the Victorian Government's Biotechnology Strategic Development Plan 2007. The objective of the BSDP Steering Committee is to build on Victoria's strong biotechnology base to generate mature, sustainable and flourishing companies that can develop products from research through to market. Members of the BSDP Steering Committee are listed below.

As a broad alliance of industry, investment and research organizations, dedicated to supporting Australia's innovative future and representing the discovery and commercialization pathway, we have seen considerable success and growth in the Australian biotechnology sector during the last decade despite a difficult economic climate. Innovation in the biotechnology sector has been one of the key drivers of converting research knowledge and technology into goods and services, increased employment and benefits to the community.

Encouragement of innovation in the biotechnology sector is therefore, one of the most critical priorities in our national quest for increased productivity and growth within this industry sector. We are concerned that the lack of recognition of biopharmaceuticals, medical devices and diagnostics within the National Innovation Priorities has the potential to result in this crucial area, with its unique and inherent needs, being treated within the broad 'Population Health' arena heterogeneous grouping that will prevent a coherent focus of policy attention.

If left unattended, we will not be able to adequately capitalize on Australia's strong innovation capabilities and performance in biotechnology, and in turn, will not be able to adequately address emerging challenges and opportunities in the rapidly growing global biopharmaceuticals, medical devices and diagnostics markets. This will have significant negative consequences for inward foreign investment, future employment opportunities and the growth of the local biopharmaceuticals sector in Australia.

Australia has a significant pool of highly trained and skilled people that assist us connect local companies and organizations to international development and partnership opportunities, influencing trade, investment and philanthropic prospects.

As a nation, we must take advantage of the sound foundation offered by our local biotechnology sector, strong infrastructure and global market focus in order to address our immediate needs and prepare for our future.

Within this framework, we recommend that the Government raise awareness of the importance of innovation within the biotechnology sector, specifically across biopharmaceuticals, medical devices and diagnostics, as follows:

1. National Innovation Priority for Biopharmaceuticals (Human Therapies and Diagnostics)

- a. We support the need for national priorities for innovation. Australia must identify and invest in its globally recognized assets for growth potential, for significant social impact and enduring commercial return.
- b. Australia's identified strengths and current success, market needs, global context, social benefit and existing infrastructure should be the principles driving the innovation priorities.
- c. We strongly advocate the inclusion of biopharmaceuticals as a National Innovation Priority on the strength of the existing sector, its success to date and its commercial and, most importantly, its social impact. The biopharmaceuticals sector fulfils all of the markers that determine a national innovation priority.

Though elements of biotechnology can be applied to a number of the identified national innovation priorities in the Cutler Review – agriculture and food security, climate change, aspects of population health and tropical solutions – a very important aspect is missing, and that is the biopharmaceuticals sector.

The addition of biopharmaceuticals as a National Innovation Priority will build on our capability for innovation through translational research and development and encourage commercial activity, job creation, export growth as well as directly address national challenges such as health costs and an ageing population.

Further, biopharmaceuticals, particularly in Victoria, is of a world-class standard supported by more than 50 years of considerable investment and development from the academic, government and private sectors.

2. R&D Tax Concession

- a. We support the proposal of the tax concession being changed from a deduction to a tax credit. The change from an after tax benefit of 7.5 cents in the dollar to 20 cents in the dollar for SMEs is a positive development and one that will make a significant difference to biotechnology companies who wish to remain Australian based. Though the increase in after tax benefits from 7.5 cents in the dollar for larger firms is small, it is nonetheless positive.

It will be important to consider the impact on larger firms who will no longer be able to access the 22% incremental R&D benefit, the ability of these organizations to carry forward unused tax credits and the affect on corporate franking accounts.

- b. We note the need to see a clarification of the term 'revenue' as well as a deeper definition of the proposed limitation of R&D tax concessions to corporate entities, excluding trusts, partnerships and unincorporated joint ventures.

3. Attracting Venture Capital

- a. While we support the proposal to expand venture capital and attract overseas capital to Australian shores, in our experience, there is a strong appetite for international venture capital co-investment only where there is an existing, well established and trusted relationship with a local investor. One example of this approach is the recent

joint investment in Chemgenex by local investor GBS Venture Partners with Alta Partners (US).

The importance of networks and relationships in this sector cannot be overstated – as well as a strong pipeline of venture capital investment-ready opportunities. Strengthening Australian links into international capital markets is therefore of vital importance and should be a strong area of focus.

- b. Many projects in the highly specialized biopharmaceuticals sector are dependent on private venture capital investment. Without the confidence that intellectual property (IP) protection gives to these investors, the development and commercialization of these products would not occur. This would have a significant impact not only on Australia's productivity but also on the health of our population. Rather than open access, a strategic approach to the management of intellectual property is recommended.

#### 4. Competitive Grants Scheme

- a. We acknowledge recommendation of the maintenance of the Innovation Investment Fund and a new round of pre-seed funds as being appropriate, as is the extension of the COMET and Enterprise Connect programs.
- b. We strongly advocate the urgent need to provide assistance to developing early stage, high risk, high growth companies who are on the critical threshold for realizing value for their technology yet are, most commonly, not in a position to attract private investment.

The benefit of the previous Commercial Ready program was to assist growing companies to leverage capital thereby reducing investment risk, increasing opportunities for investment and increasing the potential for their survival. The pre-seed funds and COMET are valuable in addressing the needs at proof-of-concept stage, for some start-up technology companies. However, biopharmaceuticals, medical device and diagnostic development companies have very different risk / time profiles and there is no initiative described in the Cutler Report that addresses this commercialization gap.

As a consequence, there is a high risk that Australia will lose a significant proportion of such companies, either by overseas relocation or failure.

- c. We propose that the Competitive Innovation Grants Program be extended to companies that are increasing value and reducing risk during the scale up stage for manufacturing first product or are in the threshold of a clinical trial. Further, the program should be extended to a \$250 million fund which would assist up to 200 companies at an important stage of development.

The proportion of Australian biotechnology companies that would be eligible, as evidenced by the number that were eligible for Commercial Ready and that had won grants, suggests the stage of development of the sector and their short term needs to cross a critical bridge to success.

Until we can collectively expand the pool of patient venture capital in this country, industry and government need to work collaboratively to ensure the survival and growth of the biopharmaceuticals, medical device and diagnostics sector.

- d. We recommend that the White Paper defines the governance of the proposed Competitive Innovation Grants program, in particular, the requirements for reporting the repayment by recipients, including the period of time, repayment conditions and the delineation between organizational profits and project royalties.

- e. We recommend the potential of a scheme in which the company does not have to pay the grant back but is able to attract matching independent funds, thus incentivizing companies to leverage government funds with private investment.

**Note** that although the BSDP Steering Committee is convened under the auspices of the BSDP through the Victorian Department of Innovation, Industry and Regional Development, the position taken by the BSDP Steering Committee and its members, as outlined in this letter, does not necessarily reflect the views of the Victorian Department of Innovation, Industry and Regional Development.

Sincerely,

On behalf of the BSDP Steering Committee members:

Dr Leigh Farrell (Vice President, Business Development, Biota Holdings Limited)

Mr Ken Windle (Chairman, Advent Pharmaceuticals)

Dr Graeme Woodrow (Chief, CSIRO Molecular & Health Technologies)

Dr Elane Zelcer (Executive Director, BioConsult Pty Ltd)

Ms Michelle Gallaher (CEO, BioMelbourne Network)

Dr Anna Lavelle (CEO, AusBiotech Limited)