CSL biopharmaceutical manufacturing
Broadmeadows, Victoria

Cochlear medical device manufacturing
Macquarie University, NSW

Joint Submission to the
House of Representatives Standing Committee on Economics
Inquiry into Impediments to Business Investment

May 2018

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Executive Summary

CSL and Cochlear are Australian success stories. They are the nation's two largest and most successful innovation-focussed advanced manufacturing companies, both actively and successfully competing globally from an Australian base.

Innovation and Science Australia's recently released 2030 Strategic Plan predicted that Australia's future prosperity will need to be driven by knowledge intensive companies that collaborate, innovate and export – companies like CSL and Cochlear.

However, in 2017 CSL and Cochlear were two of only four Australian companies to make the list of the world's top 1000 global R&D spenders[1] both with an R&D intensity of over 10 per cent. Cochlear has over 100 research partnerships across the world and CSL has more than 180 in Australia alone.

Both companies have a strong interest in enhancing Australia's international competitiveness and maximising the social and economic benefits flowing from innovation-focussed industries but competition among peer nations for advanced manufacturing and R&D is intense.

Policy makers all over the world are actively using micro and macro-economic levers to poach and fiercely compete for skilled job-creating capital investments.

The realities are stark - less than 5% of Cochlear's sales revenue is from Australia but it pays over 73% of its total tax bill here. For CSL, Australian sales revenue represents less than 10% of global external sales revenue, and its global income taxes (US$468.3 million paid in 2017) are paid in the countries where the majority of taxable income is earned.

To support the retention and growth of Australian innovation as well as large scale research, development and manufacturing, CSL and Cochlear believe Australia's public policy settings must be modern, flexible and competitive with peer nations.

By making this joint submission CSL and Cochlear are united in urging the Australian Government to conceptualise and plan for a competitive Australia, counted within the top tier of innovation nations, known and respected for its welcoming business environment, excellence in science, research and commercialisation.

This submission articulates some of the current policy challenges and makes several recommendations as to what we believe are the optimum settings for retaining existing innovation-based enterprises and building the CSLs and Cochlears of the future.

Mr David Lamont
Chief Financial Officer
CSL Limited
Group Executive Australian Operations

Mr Dig Howitt
Chief Executive Officer
Cochlear Limited

[1] Price Waterhouse Coopers, Global Innovation 1000 Study, 2017

Recommendations

This is a summary of the recommendations made in this submission, further discussion and context are included in the relevant sections as noted.

1. Constant regulatory change undermines business confidence. Governments need to be more cogniscant of the impact of change and consult carefully with impacted sectors before announcing and/or implementing reform. *(Page 6)*

2. Regulatory consistency between Australian states should be maximised. The Commonwealth should work with the states and territories to lead efforts to create a more flexible regulatory environment within Australia in order to foster innovation, including exploring specific areas for cross-jurisdictional regulatory reform. *(Page 11)*

3. A strategic and comprehensive reform of the immigration regime is necessary to support innovative Australian companies with a global export focus. There are several examples operating internationally which could be adopted *(Page 7)*

4. Government should consider revising the objects of the *Therapeutic Goods Act 1989* to include an explicit focus on supporting Australian innovation. The Therapeutic Goods Administration (TGA) should further leverage product reviews and approvals completed by trusted overseas regulators to speed up approval so that Australian manufacturers can compete more effectively in markets that require country-of-origin approval *(Page 8)*

5. Government should support ISA's recommendationand invest in developing a more effective framework to evaluate the performance of Australia in the innovation race by introducing a requirement that new government innovation programs and policies dedicate approximately 2 per cent of their budget for the evaluation of outcomes *(Page 12)*

6. Government should intensify investment and support for Australia's areas of competive advantage. This includes actively supporting and investing in existing hub/cluster initiatives which are anchored by academia and industry. Government should not try and 'force' new clusters *(Page 13)*

7. Government must maintain a strong focus on keeping Australian intellectual property onshore for as long as possible by improving the environment for translational research in Australia. It is also recommended that the Government rexamine initiatives, aimed at encouraging Australian-;based capital investment in both early stage and more mature life sciences companies. This includes the Early Stage Venture Capital Limited Partnership program *(Page 15)*

8. Australia needs to lower its corporate tax rate to an internationally competitive level or alternatively introduce discrete, boutique or targetted incentives. *(Page 17)*

CSL Limited - Background

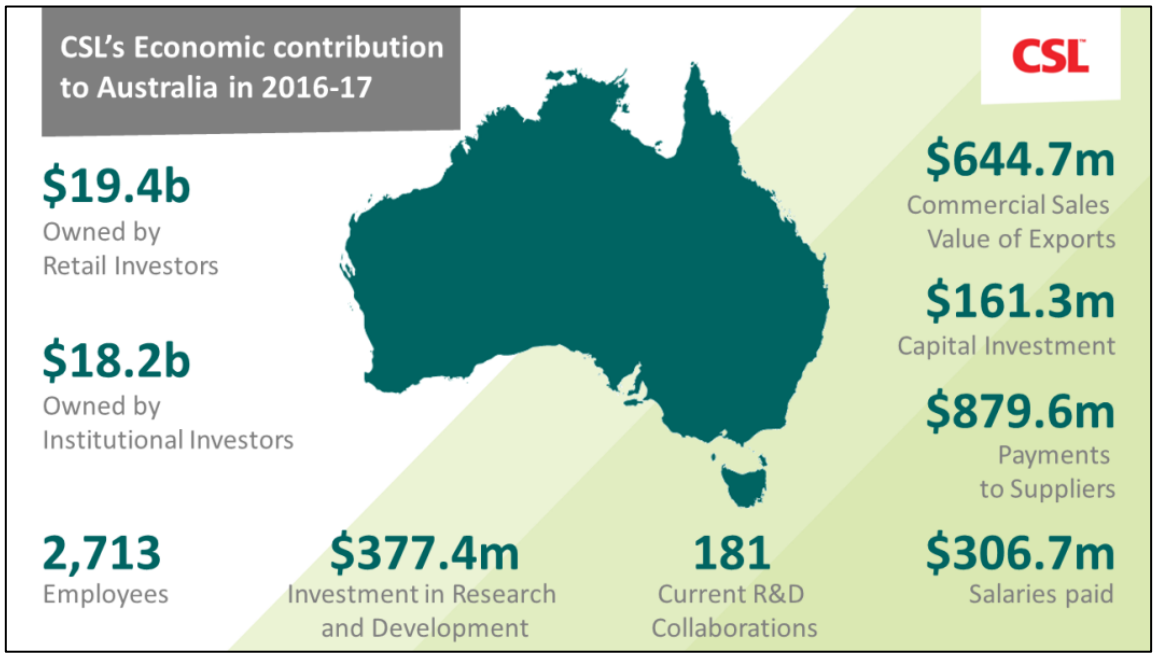
CSL Limited (ASX: CSL) is Australia's largest biotechnology company and a global leader in protein science and plasma-derived therapies.

Headquartered in Melbourne with substantial manufacturing operations in the United States, Germany, Switzerland and the UK, CSL has over 20,000 employees in more than 32 countries. CSL operates two subsidiary businesses, CSL Behring and Seqirus, which are underpinned by a significant research and development effort.

CSL Behring is a global leader in therapies derived from human plasma. It operates one of the largest human plasma collection networks in the US and manufactures plasma-derived products in Australia, the US, Germany, and Switzerland. Our purpose-built plasma products manufacturing facility in Broadmeadows, Victoria processes plasma donations for Australia (under contract with the National Blood Authority) and countries in the Asia Pacific region. The site has recently undergone a major expansion to enable processing of US-collected plasma for export as well as the production of novel synthetic clotting factors for international clinical trials.

Seqirus is the second largest company in the global influenza vaccine industry. It operates, in Parkville, Victoria, Australia's only influenza vaccine manufacturing facility, supplying seasonal influenza vaccines to Australia and global markets. Seqirus also maintains, for the Australian Government, a pandemic preparedness capability which enables the rapid development, manufacture and distribution of influenza vaccine in a pandemic emergency. Seqirus also manufactures various products of national significance for Australia, including antivenoms and Q fever vaccine, and in-licenses a broad range of vaccines and pharmaceuticals.

R&D at CSL is headquartered in Melbourne and involves more than 1300 scientists around the world. Australia is our Global Hub for Translational Medicine and Research and is home to many important collaborations with the country's outstanding academic research institutes. Each year CSL invests around 9-11% of global revenue in R&D (in 2016-17 this was $USD645 million dollars).



Cochlear Limited - Background

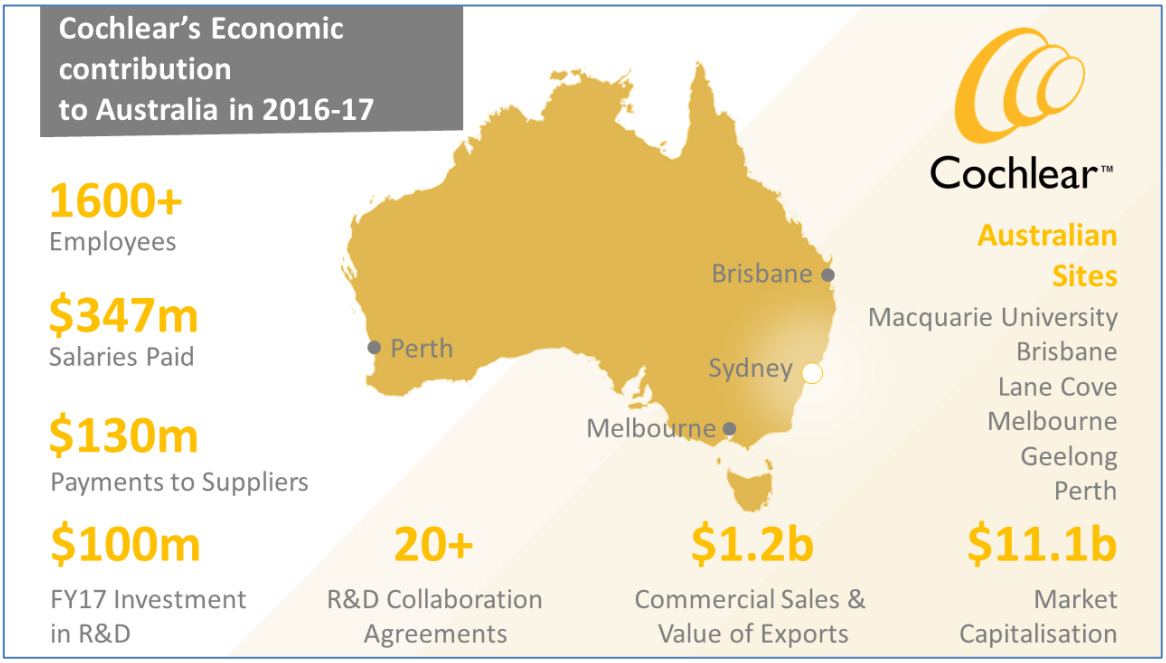
Cochlear is the global leader in the development and manufacture of implantable hearing solutions and related technology. Our range of products, including cochlear implants, bone conduction implants and acoustic implants, address different types of hearing loss in all age groups. Over 475,000 people of all ages from more than 100 countries, now hear because of a Cochlear product. This includes over 13,000 people in Australia.

Commencing operations in 1981 in the Sydney suburb of Lane Cove - where it is still has a manufacturing site - Cochlear is an Australian headquartered global company with over 3,500 employees in 30 countries across the world. Around 1,600 of Cochlear's employees are based in Australia with the majority working in manufacturing, logistics and research and development.

Cochlear's major manufacturing facility is co-located with our global headquarters on Macquarie University campus in Sydney which, together with facilities at Lane Cove and Brisbane, currently manufactures all of our.cochlear implants and cochlear implant sound processors

Cochlear invests more than AUS$150 million each year in research and development and currently participates in over 100 collaborative research programs worldwide aimed at better understanding and treating hearing loss.

While Cochlear undertakes the bulk of its manufacturing, research and development in Australia, it has research and manufacturing capability overseas including sites in the United States and Sweden as well as an advanced innovation team in Beligum. In July 2017, Cochlear announced an expansion of our global manufacturing capacity for cochlear implants with a new facility to be built in Chengdu, China. The Chengdu factory will supply China and emerging markets.



Terms of Reference 1:

What is the interaction between regulatory frameworks across all levels of Government and how can the cumulative regulatory burden be reduced to support greater business investment?

Nationally coordinated and consistent regulatory frameworks play an important role in driving business certainty and supporting mid to long-term investment decisions. Regulation can also be used to attract and retain innovative businesses. This submission highlights regulatory challenges and opportunities including;

- *Policy stability and the need for business certainty*
- *Immigration law and the importance of international talent flows*
- *The need for internationally comparable regulatory timelines*

Policy stability and the need for business certainty

Attractive regulatory regimes and business certainty are extremely important for global companies considering investment decisions.

Prior to making a significant capital investment a company's analysis and international comparison will typically include (in addition to company-specific criteria), the industrial relations regime; the intellectual property regime; the corporate tax environment; incentives for capital investment or in R&D; the trade environment; and ease of movement of human capital (visas and immigration regime).

A new multi-million dollar manufacturing plant could reasonably be expected to have a life span of 30 years or more. Therefore, the investor's confidence about the stability of the policy and regulatory settings is a very significant consideration.

Ongoing change and uncertainty around macro and micro economic regulation undermines the confidence businesses need to make multi-million dollar investment decisions.

Government needs to be more cogniscant of the impact of change and consult carefully with impacted sectors before announcing/implementing.

Recent examples of regulatory change undermining business confidence in Australia include multiple changes (both actual and foreshadowed) to the R&D tax incentive and the abolition of 457 visas without reasonable industry consultation.

Further, regulatory consistency between Australian states should be maximised. The Commonwealth should work with the states and territories to lead efforts to create a more flexible regulatory environment within Australia to foster innovation, including exploring specific areas for collaborative cross-jurisdictional regulatory reform.

Australia needs to focus on the big picture – for a nation of our size and economic weight it makes little sense for states to compete against each other for investment. Only by joining forces and focusing on each jurisdiction's area of current or potential strength can Australia seriously compete internationally. This issue is explored further in the context of Terms of Reference 2

Immigration law and the importance of international talent flows

Innovation is an internationally competitive industry. Encouraging collaboration across international borders is important, as is making Australia a desirable destination for global talent.

To compete with peer economies internationally, Australia needs a visa system that balances the protection and development of the local workforce allowing Australian companies access to international talent where it assists the transfer of skills and knowledge and; supports Australian businesses to operate at a world class standard.

Had all of the changes to 457 visas, as announced on 1 April 2017, been formally enacted they would have had a devastating effect on Australian medical research and manufacturing.

Carefully targetted sponsorship is critical to the development of capabilities in Australia and long-term business sustainability There is simply not enough large scale R&D or pharmaceutical manufacturing in Australia, outside of CSL, to genuinely support a world class talent pool. Similarly, Cochlear is the only significant manufacturer of active implantable medical devices in Australia and one of only a handful of companies in the world that makes hearing implants.

Working-visa holders occupy several critical positions at both companies including as trained and skilled professionals assisting to operate globally integrated manufacturing operations; skilled professionals filling skills gaps that cannot be recruited here because of unique activities; or internationally recognised researchers supplementing and developing Australian skills with leading-edge scientific expertise.

Restricting the ability to recruit a modest number of international personnel severely impacts innovative businesses and in the mid to long term will almost certainly reduce, not increase, the number of employment opportunities for Australians.

Thankfully, the government responded to industry advocacy and reversed a number of foreshadowed changes when the new Temporary Skills Shortage (TSS) regime was fully implemented in March 2018.

The Government has also recently announced a Global Talent Scheme (GTS) pilot aimed at providing an avenue for businesses to sponor highly skilled workers who are not eligible under the standard TSS visa. This is a positive step toward creating a credible and practical scheme that could support the pipeline of international talent for Australia's most innovative companies. However the GTS has a very high earning requirement which does not reflect that highly skilled employees may not always be highly paid even where there is a genuine shortage of those skills in the market.

In addition, our companies remain concerned about the lack of a clear and consistent pathway for intra-company temporary transfers– and the contrast between Australia's regime with the much more business-friendly regimes in the United States and United Kingdom.

CSL and Cochlear (and most other multinational companies) move employees between international facilities, for short and medium term assignments, in order to share specific expertise and improve skillsets between countries. This includes implementing global consistency, providing professional development opportunities, and upskilling in-country employees with world's best practice techniques and processes.

The US and the UK recognise the importance of a globally mobile workforce for multinational corporations and offer a specific visa for exactly this purpose. In the United States it is

called a 'L1 Intracompany Transferee Visa', in the United Kingdom it is called a 'Tier 2 Intracompany Transfer Visa'.

By contrast, Australia does not treat intra-company transfers as a separate category and requires labour market testing even where the the role is entirely unsuited to an external applicant. This adds additional cost, delay and resourcing requirements to existing operations and is pointless .

Operating in sectors dominated by European and Northern American players, CSL and Cochlear need to try and construct our Australian workforces from a patchwork of visas, shoehorning our people into occupation lists that are inflexible and outmoded. Meanwhile our competitors in the US and Europe can rely on their internal markets or intra-company transfer.

A strategic and comprehensive reform of Australia's migration regime is necessary to support innovative Australian companies with a global export focus. There are several concepts which could be adopted including the US and UK intra-company transfer visas and the concept of a two tier visa system split between domestic jobs and those exposed to export markets,

The need for internationally comparable regulatory timelines

The Australian regulatory framework for therapeutic goods, including medical devices, is not geared toward encouraging Australian innovation or supporting the development of a globally competitive advanced manufacturing sector.

The Therapeutic Goods Administration (TGA) identifies its primary responsibility as ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose[2]. Regulators in some leading jurisdictions, such as the United States Food and Drug Administration, also include supporting or facilitating innovation in their objectives or mission statements.

Patient safety must be the first priority of the TGA and Australia's robust regulatory regime offers the advantage of a reputation for safe and reliable goods. However the TGA has among the longest regulatory approval time frames for medical devices in developed countries.

Long approval times delay Australian patients' access to the latest technology – even when developed and manufactured in Australia as is the case for Cochlear's cochlear implant systems. From a business investment perspective, long approval times also delay the entry of goods manufactured in Australia to 27 other countries that require country-of-origin approval before they can begin their own regulatory approval process. These countries include China and equate to around 35% of the world market.

Start-up medical device, biomedical and pharma companies, including CSL, experience similar delays and this is a significant disincentive to commercialise new products in Australia. Start-up companies can get their products to market quicker if they manufacture in the US or Europe, even if the technology is developed in Australia.

[2] See https://www.tga.gov.au/what-tga-regulates

It is acknowledged,that the Commonwealth has recently begun implementing reforms to the regulatory system following the Expert Review of Medicines and Medical Devices Regulation3 This includes a new "express pathway" for truly novel & innovative technologies.

The size of the Australian medical technology sector means it will always be difficult if not impossible for the TGA to employ enough highly skilled and experienced assessors to be truly world-leading in its own right.

However, a recent key reform designed to help the TGA better leverage overseas expertise in the approval process – and which could have had major benefits for Australian medtech's gobal competitiveness - has been undermined by unduly cautious implementation..

In 2014 a new approval pathway was introduced enabling the TGA to recognise certification from EU Notified Bodies for Australian medical device manufacturers. This process was intended to help streamline approvals but in 2016 was taking longer on average than a full conformity assessment (see table below)

Application Type	**Mean Processing Time**	**TGA's Target Processing Time**	**Approx. TGA Fee**
TGA Conformity Assessment	118 work days	120 work days	$57,000
TGA Application Audit (CE certified devices)	171 work days	60 work days	$7,000

Based on current performance figures4 the relevant application audits are taking a mean (average) of 94 TGA work days, with a median of 56 work days (i.e. 50% are completed in less than 56 work days, and 50% are completed in more than 56 work days).The TGA is failing to meet its own target in around half of all applications.

KANSO CASE STUDY

Cochlear's latest off-ear sound processor product, Kanso™ was approved by the TGA on 16th November 2016. This product received European CE certification in April 2016 and FDA approval in September 2016, and has been available in markets that accept CE and FDA approval from around those dates. Regulatory approval took 4 months in Europe, and a further 6 months in Australia – well over the 3 month target date for these applications. This was because the requirement for Level II audits of class III and active implantable medical devices that are already CE marked (by a reputable European Notified Body) triggers a duplicative review of clinical data. Slower approval times in Cochlear's home jurisdiction undermines its global leadership position in the cochlear implant industry and puts Australian-based manufacturers at a competitive disadvantage compared with overseas manufacturers. They can obtain freely obtain Cochlear's newest innovations and begin replicating its features before it can be sold in Australia and 27 other countries.

It is acknowledged that this case study was two years ago and there have been improvements to processing time

[3] The independent review was undertaken by a panel of three experts – Emeritus Professor Lloyd Sansom AO, Mr Will Delaat and Professor John Horvarth AO. The Review Report was delivered to the Health Minister on 31 July 2015.

[4] TGA Half Yearly Performance Snapshot 1 July-31 December 2017

To best serve Australian consumers and manufacturers, our regulatory system should ensure the TGA leverages product reviews and approvals completed by trusted overseas regulators so that:

- all medical devices are accessible on the Australian market as soon as possible, and,

- Australian manufacturers receive TGA approval as quickly as possible so they can compete with EU and US competitors in markets that require country-of-origin approval.

The vision for Australia's regulatory approval system must be more ambitious and more focused on supporting innovation. Ensuring approval times are comparable to world leading practice, while maintaining public safety, would offer a strong competitive advantage for Australian companies. This would mean accepting the inherent limitations of the Australian environment and relying more on the expertise of trusted overseas regulators. We also recommend the Government consider revising the objects of the *Therapeutic Goods Act 1989* to include an explicit focus on supporting Australian innovations.

Terms of Reference 2:

What is the impact of innovation policies, at the Commonwealth and State government levels, on business investment and the role of innovation policies in encouraging greater business investment, having regard to approaches taken in other countries?

Innovation policy and a clear, coordinated focus across government is important to support, encourage, attract and retain innovative industries particularly large scale research and advanced manufacturing. Australia is not the only developed economy to be concerned about where its economic growth is going to come from over the next 30 years. It is, however, one of the few not actively using economic levers, at both a broad and a boutique level, to fiercely compete for job-creating investments by innovation focussed industries.

This submission highlights the challenges and opportunities of innovation policies including;

- *The need for national coordination and policy consistency*
- *The importance of clusters and hubs*
- *Why government should continue to invest in basic research*
- *Focus on keeping intellectual property onshore*

National coordination and policy consistency

There is a need for greater collaboration, coordination and consolidation between and within the Commonwealth and states and territories on innovation strategy, policies and programs.

Over the past five years there has been a proliferation of of strategies and intiatives (including funds and grants) for innovation more broadly and the medtech and advanced manufacturing sectors specifically. A non-exhaustive snapshot is provided below:

	Strategy/Plan/Initiatives	Initiative/Fund/Grants
Commonwealth or National	Australia 2030: Prosperity through innovation (2018) Performance Review of the Australian Innovation, Science and Research System (2017) Medical Technologies and Pharmaceuticals Roadmap (CSIRO 2017) Medtech, Biotechnology and Pharmaceutical Sector 10 Year Competitiveness Plan 2016 (MTP Connect) Advanced Manufacturing 10 Year Sector Competitiveness Plan 2017 (AMGC) National Innovation and Science Agenda Global Innovation Strategy	National Health and Medical Research Council (NHMRC) Australian Research Council (ARC) Biomedical Translation Fund Medical Research Future Fund CSIRO Innovation Fund Cooperative Research Centres/Innovative Manufacturing CRC Grants National Collaborative Research Infrastructure Strategy Global Innovation Strategy Medical Research Commercialisation Fund
NSW	NSW Innovation Strategy (2016) Manufacturing Industry Action Plan – Manufacturing Industry Taskforce (September 2012) The MedTech Blueprint – building a strong industry for Australia's economic and social future (Med Tech Knowledge Hub) 2016 NSW Government Response to NSW Health and Medical Research Strategic Review (2012)	Medical Device Commercial Training Program Medical Devices Fund NSW Medical Research Support Program Boosting Business Innovation Program Research Attraction and Acceleration Program Minimum Viable Product Grants; Building Partnership Grants Accelerating Growth Loans; Regional Growth Loans: Strategic Growth Loans; Loan Guarantees TechVouchers
Victoria	Medical Technologies and Pharmaceuticals Sector Strategy (2016)	Victorian Future Industries Fund Future Industries Sector Growth Program Advanced Manufacturing Voucher Stream Future Industries Manufacturing Program
Queensland	Queensland Advanced Manufacturing 10 Year Roadmap and Action Plan (Dec 2016) Queensland Biomedical 10 Year Roadmap and Action Plan (June 2017) Queensland Science and Research Priorities (June 15)	Advance Queensland Industry Attraction Fund Biomedical Assistance Fund; Biomedical Voucher Scheme Business Development Fund Innovation Partnership grants

While several of these programs are well-targetted and are proving effective, many have been developed and implemented without sufficient coordination or consolidation at the state and Commonwealth level. Industry is facing an increasingly crowded policy and program landscape that can be confusing to navigate particularly for start-ups and small to medium enterprises (SMEs).

Recently there has been a laudable emphasis on start-ups and taking new companies to the commercialisation phase but there has been scant attention paid to the longer life-cycle of high growth companies (such as biotech, medtech and pharma) and ensuring they stay (and invest) in Australia.

Further, the routine disbanding and re-creation of programs and funds when new governments are formed or new ministers appointed - without a systemic review of the effectiveness of existing policy or the cost-benefit of new programs – is frustrating and self-defeating.

While challenging from a political perspective, taking a national approach that harnesses the strengths and responsibilities of each jurisdiction, would better support Australia's global competitiveness.

In August 2017, the Council of Australian Governments (COAG) Industry and Skills Ministers agreed to national innovation objectives to leverage Australia's efforts and investments on innovation.

> *"The Commonwealth, states and territories will work together to improve complementarity of existing arrangements and leverage state and territory networks, expertise and experience by building and fostering: • business simplification • skills and talent and entrepreneurship • innovation infrastructure • collaboration • investment • sectors of future opportunity for competitive strength and strategic priority."*

While this demonstrates intent to improve coordination, the objectives are very high level and there are yet to be any significant concrete outcomes from this agreement.

Improvements to national innovation policy should include a focus on consistency and clarity in programs and initiatives – ensuring there are clear objectives and KPIs for funds and grants and, that strategies and plans are implemented and reviewed.

To that end, we support Innovation and Science Australia's recommendation that government invest in developing a more effective framework to evaluate the performance of Australia in the innovation race by "*introducing a requirement that new government funding programs and policies aimed at supporting innovation dedicate approximately 2 per cent of their budget for the evaluation of outcomes that should be clearly identified in advance*"[5]

The importance of clusters and hubs

In the medical research and technology sector, clusters of geographically close or co-located research and clinical facilities can be highly significant.

[5] Recommendation 29 Innovation and Science Australia: Australia 2030 Prosperity through Innovation, January 2018, p 100

Innovation depends on the exchange of ideas among individuals and in research, the ecosystems created by the co-location or geographic closeness of pharmaceutical/medtechcompanies, research institutes, hospitals and world-class universities attract researchers, research funding and can act as an incubator for innovative start-up companies and, a valuable source of 'knowledge spillovers' (when a given company's innovation stimulates related inventions and technical improvements by other companies).

CSL maintains it's Global Hub for Translational Medicine and Research in Victoria largely because of the Parkville biomedical cluster and the high quality of intellectual property that this ecosystem generates. CSL is a significant contributor to the cluster via its own Parkville (research and manufacturing) facilities and through its partnership in the University of Melbourne's BIO21 Molecular Science and Biotechnology Institute. The Institute is currently undergoing a significant expansion to house additional CSL R&D.

The Parkville cluster houses more than 30 world-class hospitals, medical research institutes, bio-medical organisations and universities. It employs 49,000 people and is considered a world-class biotech precinct and a significant research presence in global terms.

Cochlear's global headquarters, its primary manufacturing facility, and its core research and development teams are all located at the Macquarie University campus in Sydney. Cochlear is a founding partner of the Australian Hearing Hub (AHH) which is adjacent to Cochlear HQ and was underpinned by a $40 million investment from the Australian Government.

The AHH is an initiative of Macquarie University and brings together leading researchers and health care organisations – including Australian Hearing, the National Acoustic Laboratory, the Royal Institute for Deaf and Blind Children and the Shepherd Centre - with the objective of being a global centre of excellence for understanding and treating hearing loss. Further, Macquarie University Hospital is home to both hearing implant related clinical research and surgery conducted by some of Australia's leading surgeons.

The AHH is a micro-precinct sitting within the broader Macquarie Park Innovation District which is home to 180 large life science, technology and digital corporations and 200 small businesses employing over 45,000 people and producing an economic output of $9.2billion in 2017.

From a talent retention and recruitment perspective, both companies find that researchers enjoy being located in a wholly research environment and appreciate access to peers and colleagues at universities and neighbouring research institutes plus the associated opportunities for intellectual conferencing, professional development and continuing education.

At their meeting in April 2018 the COAG Skills and Industry Council agreed to "*principles which support place-based innovation policies. This will help drive collaboration and innovation and ensure complementary activities in supporting innovation precincts*" (Communique April 2018).

While the detail of these principles remain unknown, this agreement is encouraging insofar as it supports coordination and prioritisation at a national level. While we agree healthy levels of competition are essential to growth, each jurisdiction should be supported to build on existing strengths and areas of competitive advantage. This includes continued active support and investment in existing precincts, clusters and hubs particularly where they are jointly anchored by academia and industry.

We also note ISA's Australia 2030 Strategic Plan recommended the Australian Government "*develop and release an Australian Innovation Precincts Statement to shape Australian Government involvement in emerging localised innovation ecosystems in cities and regions"*[6].

It is not recommended that governments try to 'force' or 'create' new clusters, as they do need to be anchored by multiple complementary insitutions. In making investment decisions, such as the building of a new hospital, government should wherever possible be cognisant of existing or emerging clusters and try to co-locate new facilities.

Government should continue to invest in basic research

Basic research is the first R&D step. It is not typically immediately directed towards a commercial product, but rather towards an understanding of the basic science that might in due course form the basis for translation into clinical practice and/or a commercial product.

Basic research is typically characterised by large knowledge spillovers. In fact, one of the defining characteristics of basic research is that it is deliberately published so that others can build upon it.

Because there are large spillovers that cannot and arguably, should not, be captured, private firms are typically unwilling to invest in basic research; they cannot capture a sufficient share of the value of the research to make it commercially worthwhile. Government therefore plays an important role in funding a sufficient level of basic research which then form the essential cornerstones of innovation, knowledge spillovers and IP that can be developed into commercial (life-changing and life-saving) products.

Australia's basic research sector — primarily universities, research institutes and the CSIRO, all of which are predominantly government funded — is highly productive, internationally connected, and recognised globally for its high quality research.

The level and availability of Australian Government support for universities and research institutes has been and remains important in making Australia a high quality centre for R&D. These institutions also help train and develop a pool of highly skilled scientists and researchers entering the work force; further funding therefore helps increase the size of the skills base on which the innovation economy relies.

It is of significant concern that the success rates for NHMRC grants have fallen to extremely low levels – 15 per cent in 2017. This funding is at the epicentre of Australia's biotech/medtech ecosystems and when the basic research institutions are starved of funds it has a knock-on effect and not only risks good ideas and good people going elsewhere, but the very reason for a hubs existence is threatened.

A strong focus on funding basic research through the NHMRC with the addition of new inititiatives such as the Medical Research Future Fund for translational research, and large complex initiatives should help to avoid further drop-out of early- and mid-career researchers and keep the diversity of research programs in Australia.

[6] Recommendation 23 Innovation and Science Australia: Australia 2030 Prosperity through Innovation, January 2018, p 80

Focus on keeping intellectual property onshore

CSL and Cochlear believe that Australia's medical and life sciences research community is a rich source of potential new discoveries to address the world's unmet medical needs.

However, Australia does not currently reap the maximum social and economic value from its research base because too often Australian intellectual property is either not translated from an idea into a product or, it goes offshore for development at a very early stage.

Intellectual property at the pre-translational stage is far less valuable (economically and socially) than that same intellectual property at the post-translational stage. When Australia underwrites early research but does not reap the post-translational rewards it could be argued that Australia is under-writing research for the rest of the world to reap the development and commercialisation benefits.

The newly established Biomedical Translation Fund (in which CSL is one participant) is a good initiative to begin to support and finance more translational research onshore. It will certainly increase the likelihood that the large investment government makes in tertiary education and basic research will translate into projects that can be taken through to patients/market (or at least closer to patients) by Australian firms.

It is recommended that Government keep a strong focus keeping Australian intellectual property onshore for as long as possible by improving the environment for translational research in Australia. This should include access to world class research infrastructure.In addition to the BTF venture capital model we suggest that once the Medical Research Future Fund is fully funded and established, at least 20% of its annual $1 billion disbursements should be allocated to translational research.

We also recommend the Government re-examine initiatives aimed at encouraging Australian based capital investment in both early stage and more mature life sciences companies. For example, Cochlear's experience in attempting to enter the venture capital industry utilising the Early Stage Venture Capital Limited Partnership (ESVCLP) effectively disincentivised a successful Australian innovator from investing in Australian start-ups (see case study below)

Early Stage Venture Capital Limited Partnership Case Study
The Early Stage Venture Capital Limited Partnership (ESVCLP) program provides ESVCLPs with a flow-through tax incentive and a tax exemption on an investor's share of a fund's income to increase investment in early stage venture capital businesses. While initially the program was aimed at attracting foreign capital, in 2007 the ESCVLP was expanded to incentivise Australian-based early stage venture capital.

In 2017 Innovation and Science Australia's Innovation Investment Committee declined to register Cochlear and its investment partners Macquarie University and RIDBC under the ESVCLP program. This was because Cochlear's investment exceeded 30% of the total committed capital. Under the relevant legislation only exempt financial institutions are able to exceed this amount. However the Board may also exercise a discretion to allow a partner to exceed this amount. It had not previously exercised the discretion, declined to on this occasion and still has not.

We recommend the Government issues guidelines (as provided for under the *Venture Capital Act 2002*) to ensure the Board can provide exemptions for widely held companies who demonstrate an active, sizeable commitment to Australian innovation. Alternatively, an initiative to support corporate venturing should be developed.

In the medtech/life sciences sector not enough of the highest quality intellectual property and companies are staying in Australia and contributing sustaining jobs and economic value for the long term. This is partly due to a lack of coordination and purpose from government financial support as well as insufficient patient capital.

More venture capital is not necessarily the only answer as venture captial generally seeks increased value in the shortest time possible to create a high rate of return. Government should consider an initiative aimed at encouraging the investment of Australian-centric, patient capital in mature life sciences companies in a way that will anchor their headquarters and a significant part of their operations in Australia for the longer term.

Terms of Reference 3:

What is the role that taxation policy, at the Commonwealth and State government levels, can have on the encouragement of new business investment?

International competition for capital investment is fierce. Australia with an overall corporate tax rate of 30% and zero differential or boutique offerings in exchange for investments and jobs is becoming increasingly isolated as a high-tax jurisdiction uncompetitive internationally and particularly when compared to our closest peer nations (UK, USA) or geographic nations (Singapore).

This submission highlights the challenges and opportunities of taxation policy including;

- *The need for an internationally competitive taxation regime*
- *Why anchor tenants and large manufacturers should be supported*
- *Tax incentives for research and development*

The need for an internationally competitive taxation regime

To create the incentive to invest in money-making (aka tax-paying) ventures (eg. large scale manufacturing for global markets), or to hold revenue-generating intellectual property onshore, it is imperative that Australia mirror or mimic corporate tax rates now being offered internationally.

Peer nations are using various taxation concepts to appeal to innovation focussed companies and this submission does not attempt to rank or rate the various models – rather, it merely highlights some of the regimes being offered internationally, the impact these can have on the NPV of a project, and the aggressive and successful way these are being marketed to companies who invest internationally.

An overall reduction in corporate tax rates is now standard practice internationally. From 2017, the UK corporate tax rate is 19% (reducing to 17% in 2020), from 2020, the French corporate tax rate is 28% (reducing to 25% in 2022), and from 2018 the US Federal tax rate is 21%. The Australian corporate tax rate is 30%.

The difference between locating advanced manufacturing in a lower-tax jurisdiction or Australia, in net present value over the lifetime of a major project, would routinely be in excess of hundreds of millions of dollars and, as previously published, in the case of CSL's recent recombinant product manufacturing investment in Switerzland, it was in excess of $AUD1billion.

Australia needs to lower its corporate tax rate to an internationally competitive level if it wants to remove one of the most obvious and critical barriers to significant capital investments in Australia (particularly those originating offshore). Better still, an alternative to across-the-board reductions are the discrete, boutique or targetted incentives which are also now being offered in many countries (and which in most circumstances are very significantly below the standard rate).

Patent Boxes are very commonly offered to incentivise the retention of profit-making

intellectual property by appling a reduced rate of tax (10% in UK) on income deriving from the commercial exploitation of patents.

Other countries offer 'inward investment support', they target attractive investments and offer special rates, benefits and support in exchange for agreed deliverables such as capital investment and employment.

The aim of having competitive tax rates is to attract investment to Australia instead of having it go to peer nations – all of whom are equally looking to innovative industries in order to generate new skilled employment, help offset the decline in conventional manufacturing, capitalise on valuable government investment in R&D and education, and thereby contribute to the broader economy.

'Anchor tenants' and large manufacturers are worthy of special consideration.

The importance of larger manufacturers (being the end, commercialisation stage of research and development) should not be underestimated.

Large manufacturers act as anchor tenants for research precincts, attract other researchers and business and it is well recognised they generate significant spillover benefits and positiive externalities.

Further, these large businesses have a genuine business reason to actively support the research and development ecosystem (including STEM education).

The concept of discrete incentives to attract and retain anchor tenants is well recognised internationally and should not be dismissed by the Australian government.

Tax incentives for research & development

Australia's basic research sector, primarily universities, research institutes and the CSIRO, all of which are predominantly government funded, is highly productive, internationally connected, and recognised globally for its high quality research. This, in conjunction with the R&D Tax Incentive, makes Australia an attractive place for early stage commercial R&D.

Yet overall Australian investment in innovation/R&D, both by government and business, needs to increase.

Australia's gross expenditure on R&D (GERD) is currently at about 1.8% while top performing nations are around 3.69%. Business expenditure on R&D (BERD) is particularly low (1.01% as at 2015). This needs to dramatically improve if we are to be real competitors in the innovation race. As noted by ISA "*Australia is going against the global trend for national BERD growth to exceed GDP growth*"[7]

CSL and Cochlear both maintain their global centres of R&D in Australia and the level and availability of government support has been, and remains, important in making this an attractive high quality centre for R&D.

[7] ISA Report p 39

The sustainability of both businesses depends on maintaining a pipeline of prospective products in various stages of development which may, or may not, become products for sale into global markets. Significant risk is a hallmark of medical research.

Australia competes with several peer economies for R&D investment and the tax incentive is a significant influence for commercial operations like CSL and Cochlear to conduct R&D here and to maximise the amount of that investment.

Yet despite evidence that R&D expenditure tends to have a positive effect across all industries on growth in turnover, labour productivity and wages, the Australian Government's support and incentives for business expenditure in R&D has been significantly cut in the past five years.

This includes the introduction of an annual $100m expenditure cap per claimant (2015), a 1.5% reduction in the offset rate (2016), plus the various cuts and reductions recommended by the Review of the R&D Tax Incentive (the 'three Fs report') in September 2016.

A drop in BERD has coincided with these changes[8]. As the Australian Innovation System Report 2017 noted "Australia's BERD investment grew strongly from a relatively low base in the 1990s and 2000s but the BERD-to-GDP ratio has declined sharply from its peak in 2008–09. Most recently Australian businesses spent $16.7 billion on R&D in 2015–16 compared to $18.9 billion in 2013–14, a decrease of 12 per cent in current prices".

CSL and Cochlear, however, continue to maintain high levels of expenditure as percentage of revenue/expenditure particularly compared to Australian peers and, to increase their total expenditure on R&D. This is because our companies have been built on R&D and we must continue to invest to compete and grow internationally.

For the purposes of the R&D tax incentive, in 2016/17 CSL's qualifying R&D expenditure was AUD $100m (from a global R&D spend of $USD645m). Cochlear's eligible expenditure was $AUD100m (from a global R&D spend of $AUD152m).

While neither company desires to reduce our investment in R&D; as global companies with expertise and capability offshore, we do have choice about where we invest. This became a very real and sensible consideration as both companies reached the $100million limit for tax incentive-eligible expenditure.

The announced intention of the 2018/19 Budget, to increase the cap on eligible expenditure to $150 million is warmly welcomed, although a cap at any level is an arbitrary line in the sand after which there is no economic incentive to increase investment onshore.

Both companies regularly receive offers of various incentives to perform R&D offshore and we suggest that proactive policies to retain and incentivise the sort of real, intensive, R&D performed by these companies should be core to Australia's industry policy.

When Australian businesses place new R&D offshore, it means intellectual property moves offshore, tax is paid offshore and highly desirable R&D jobs are added outside Australia.

[8] Australian Innovation System Report 2017, Office of the Chief Economist, p 70

Further Information

CSL and Cochlear would be happy to provide further information or participate in public consultations as required.