Australian Medical Manufacturing Exporters Coalition

Pre-Budget Submission

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1. Introduction

In 2020, Australian medical research and Australian medical manufacturers have been at the centre of our nation's response to the global COVID19 pandemic.

ResMed rapidly pivoted its Australian manufacturing operations to produce thousands of ventilators. CSL, the last onshore industrial scale human biologics company, is manufacturing two COVID vaccine candidates and a hyperimmunue therapy for use by the Australian population.

But October 2020 also saw two of the last remaining multinational pharmaceutical manufacturers announce closure of their local facilities. The loss of GSK's Boronia, Victoria blow-fill-seal plant will cost 300 direct jobs[i] and many more in the Victorian supply chain for medical manufacturers. Pfizer's decision to close its Bentley, Perth plant will cost 470 direct jobs plus those in its supply chain. Pfizer's facility used to manufacture pharmaceuticals for export to North America, Europe, Africa, Latin American, Asia and China[ii].

It is simply no longer possible to ignore that unless the business environment is made more internationally competitive, Australia will struggle to be able to retain, attract or resurrect Australian medical manufacturing at any significant scale. This erosion of Australia's medical manufacturing base is occurring at a time when the benefits the sector can offer Australia – the creation of highly paid jobs, export opportunities, skills development and medical supply sovereignty – are the very things Government sees as priorities.

Australia will continue to struggle to compete with comparable nations for advanced manufacturing without considering how it is taxed. Although the political realities of changing the corporate tax rate are accepted, while Australia maintains one of the world's highest corporate tax rates, it will simply not be competitive in global markets. The average top corporate rate among EU countries is 21.77 percent and 23.59 percent in OECD countries. In the US it is 20%.

Many countries have mitigated any relative disadvantage they suffer through higher tax rates. They do so by incentivising high value investments in advanced manufacturing, by offering lower tax rates when the revenue is earned through locally developed intellectual property. Such nations include the United Kingdom, France, Switzerland, Singapore, Israel, Ireland, India, China, Andorra, Belgium, Cyprus, Greece, Hungary, Italy, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Slovakia, Spain, Turkey, South Korea and Vietnam.

Globally, of the 33 countries that provide 'front-end' tax incentives for eligible R&D costs (like the Australian R&D tax incentive), 24 also provide IP tax incentives to assist in the commercialisation of the IP generated.

Taking this approach removes the necessity of lowering corporate tax rates across the economy but encourages sought after activity in an area such as medical manufacturing that has specific national interest considerations.

Importantly, it is also a market based solution that allows the natural expansion of the sector without constant intervention, while leveraging Australia's globally recognised expertise and investment in medical research[iii].

The Australian Medical Manufacturing Exporters Coalition welcomes the announcement of the Modern Manufacturing Scheme and are heartened that the approach is expected to include a competitive taxation system.[iv]

2.0 The Australian Medical Manufacturing Exporters Coalition

The Australian Medical Manufacturing Exporters Coalition (AMMEC) comprises Australian medtech and biotech manufacturers and industry associations. Companies include Australia's largest and most successful medical manufacturers, plus small to medium enterprises looking to innovate and expand from an Australian base.

ALL members of the coalition have a strong interest in enhancing Australia's international competitiveness and maximising the social and economic benefits flowing from innovation-focussed industries and specifically medical manufacturing.

Atomo Diagnostics

Atomo Diagnostics was established in 2010 to transform rapid diagnostic testing (RDT) through the design and manufacture of innovative integrated blood-based devices. Atomo listed on the ASX in April 2020. Headquartered in Sydney, where all of its global R&D activities are located, Atomo develops and manufactures a range of rapid tests for applications including COVID and HIV. Atomo supplies its award winning products to Australia plus global partners in Europe, North America and Asia as well as to Africa where it is a leading supplier of WHO prequalified HIV self-tests.

AusBiotech

AusBiotech is Australia's life sciences organisation, working on behalf of members to provide representation and services to promote the global growth of the Australian life sciences industry. AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), digital health, food technology and agricultural sectors.

AusBiotech is dedicated to the development, growth and prosperity of the Australian life science 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.

Cochlear Limited

Cochlear is the global leader in implantable hearing solutions with products including cochlear implants, bone conduction implants and acoustic implants. Commencing operations in 1981 as part of the Nucleus group, today Cochlear is a Top 50 ASX-listed company with annual global revenues of

AUD$1.4 billion. Selling in over 180 countries, Cochlear has provided more than 600,000 implantable devices, helping people of all ages to hear. Headquartered at Macquarie University in Sydney, we currently undertake more than two thirds of our research & development (R&D) and manufacture more than 85% of our products in Australia. Cochlear has more than 4,000 employees around the world with over 1,700 employees in Australia based largely at sites in Sydney and Brisbane. located with their 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

Cook Medical

Established in 1979, William A. Cook Australia has more than 600 employees in manufacturing, distribution, engineering and technical specialties. The company exports more than 90% of its locally manufactured products to medical providers around the world with devices across two product families: endovascular grafts for the treatment of vascular disease and in-vitro fertilisation to assist those trying to conceive a child.

CSL Limited

CSL Limited 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. R&D at CSL is headquartered in Melbourne and involves more than 1300 scientists around the world.

CSL Behring

CSL Behring manufactures plasma-derived products in Australia, the US, Germany, and Switzerland. Their 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. It also manufactures US-collected plasma into commercial therapeutics for export.

Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse with products ranging from familiar items such as syringes and wound dressings, through to high-technology implanted devices such as pacemakers, defibrillators, hip and other orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines.

Nanosonics

Nanosonics is an Australian medium-sized medtech company specialising in unique, automated technology for the high level disinfection of intracavity and surface ultrasound probes. Nanosonics technology is used in North America, Canada, the United Kingdom,

Ireland, Germany, France, Belgium, Italy, Denmark, Russia, Singapore, Hong Kong, Japan, Mexico, Australia and New Zealand.

Polynovo

Polynovo Limited is an Australian based medical device company that designs, develops and manufactures (in Melbourne) dermal regeneration solutions using its patented NovoSorb biodegradable polymer technology. Their development program covers Breast Sling, Hernia, and Orthopedic applications.

Prism Surgical

Prism Surgical is a medium-sized Australian owned designer, developer and manufacturer of innovative spinal implant technologies to both the Australian and International markets. It is the company's commitment to offer both comprehensive and bespoke spinal care solutions for the treatment of simple and complex spine pathologies.

With its Australian manufacturing partner, Prism Surgical currently manufactures 100% of its implantable devices here in Australia and undertakes all of its R&D in Australia. Prism has expanded its commercial footprint into the United Kingdom and is currently pursuing opportunities into the USA market. With this in mind, Prism Surgical is exploring various international markets that offer more attractive R&D and commercialisation environments

ResMed

ResMed is a world-leading medical device manufacturer for sleep and respiratory conditions. ResMed was Australian-founded and is headquartered in the United States. It undertakes R&D and / or manufacturing operations in the United States, Singapore, Ireland and Australia. Each of these locations have a lower tax rate than Australia and greater incentives for commercialisation.

Seqirus

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 manufactures various products of national significance for Australia, including antivenoms and Q fever vaccine, and in-licenses a broad range of vaccines and pharmaceuticals.

3.0 Proposal to Stimulate Australian Medical Manufacturing

The Australian Medical Manufacturing Exporters Coalition believe the below recommended intitiative would:

- Meet Government's stated objectives of supporting local advanced manufacturing and domestic capability in critical medical and biotech products.

- Counter the offshoring of Australian intellectual property and loss of long-term highly paid, highly skilled jobs, and tax revenue.

- Mitigate Australia's currently uncompetitive policy environment for the commercialisation of medical research compared to peer nations such as the UK, US, Switzerland, France, Singapore etc.

- Introduce a policy initiative focussed on the revenue-generating phase of the medical research value chain.

Background

Australia is progressively falling in annual Global Innovation Index (GII) rankings despite ranking 13th in terms of Government tax and direct funding support for R&D. The nation moved from 18th place in 2011 to 20th in 2018 and now 23rd in 2020[v]. This trend relative to other developed nations means significant economic activity is being lost to peer nations. Specifically, opportunities for well paid jobs in advanced manufacturing plus license and royalty payments are being exported.

As an element of its Covid-19 response, the Morrison Government has determined that local capacity in medical and health supplies is a sovereign risk issue. Australia has world-recognised expertise in medical research – ranking in the top 10 for institutions and human capital & research in the GII . However, current public policy settings disincentivise the onshore commercialisation and manufacturing of that research. This is in stark contrast to other advanced nations which heavily incentivise commercialisation.

Presently the Australian taxpayer, via the R&D tax incentive, the Medical Research Future Fund, and the National Health and Medical Research Council (NHMRC) spends significant amounts to support medical break-throughs (over $3B in FY18/19). However, there are currently no incentives for on-shore commercialisation of the resultant IP. Without a change in policy, Australia will continue to effectively underwrite and de-risk commercialisation opportunities for other nations.

This document outlines a proposed policy – a Medical Manufacturing Incentive (MMI) - to address this imbalance. It is targeted at the Australian medtech and biotech industries. Its aim is to decrease the flow of Australian medical intellectual property overseas and underpin the local growth of highly-paid advanced manufacturing jobs, capital intensive investment and sovereign capacity in medical technology and biotechnology manufacturing.

The Value Chain in Medical Research Commercialisation

The development of medical intellectual property from early research, through clinical trials to full-scale manufacture and export is a clearly defined value chain.

During pre-revenue development (from early research through clinical trials) research costs are very high, employment is limited to small numbers of highly specialised researchers and outcomes are uncertain.

In contrast, when products progress to manufacture and sale (when most Australian IP

currently goes offshore), the economic returns are substantial. Manufacturing as well as ownership of the intellectual property offers substantial economic benefits to the host nation through royalties, license fees, supply chains, jobs, capital investment, and local manufacturing capacity.

The above graphic illustrates this value chain. Specifically, it highlights that current Australian Government support tapers at the point of greatest potential social and economic benefit to the country. As a result, it invites the export of IP to other countries and is fundamentally self-defeating to the national interest.

Overseas Incentive Schemes

The highly mobile nature of IP means entrepreneurs can readily choose the location in which they commercialise research outcomes. As a result, taxation-based incentives are a subject of significant global interest.

Over the past twenty years, many jurisdictions directly comparable to Australia (developed, high wage, high cost economies) have introduced special tax incentives designed to encourage the local commercialisation of IP by reducing the effective tax rate on IP related profits.

European countries have introduced IP tax incentive policies to alleviate unfavourable tax elasticity, remain competitive and to reduce the loss of IP related tax revenue. IP tax incentives now feature very prominently throughout Europe, with 15 of the 28 European Union member states, currently offering an IP tax incentive. The most recent has been the Swiss 'patent box' which came into effect as of 1 January 2020.

Outside of Europe, IP tax incentives have been implemented in countries including India, Singapore and Israel. Countries such as Canada and the United States are also considering this policy option.

To ensure compliance with OECD anti - Base Erosion and Profit Shifting (BEPS) requirements countries may only offer these incentives to an entity if substantial R&D activity resulting in that IP was conducted domestically.

Notable examples found in the United Kingdom, Ireland and France are detailed below:

United Kingdom – "Patent Box"
A Patent Box regime was introduced in the UK for profits earned on or after 1 April 2013 from patented inventions and certain other innovations. The regime effectively applies a 10% rate of corporation tax to profits generated from qualifying patents. Claimants must track their UK R&D expenses and how they relate to the specific patents, products, or product families.

Ireland – "Knowledge Development Box"
Ireland's knowledge development box (KDB), reduces the tax rate on the profits attributable to the invention to 6.25% (compared to the standard 12.5% Irish corporation tax rate).

France – "238 of the General Tax Code"
Income and capital gains arising from patents (acquired or created) are taxed at a reduced corporate tax rate of 10% (the standard tax rate currently being 30%, to which specific levies are added), regardless of where the R&D expenditure is incurred.

Possible Features of an Australian Scheme

The proposed MMI model for Australia borrows heavily from the many 'patent box' schemes, specifically the United Kingdom model.

The broad perimeters of the MMI are recommended to be:

- Eligible IP to include patents, agreed non-patent IP regulatory protection, and copyrighted software.
- IP holding conditions would include full ownership or exclusive licence.
- Effective tax rate of 10% (equivalent to the UK and French schemes).
- Qualifying income would include to include royalties, licence fees, sale of qualifying IP, sales of patented items (product sales), IP derived income (e.g. from patented services) and infringement income.
- R&D definition would be linked to the definition in RDTI legislation (qualifying expenditure to include overseas clinical trial expenses)
- MMI benefits to cease upon expiry of the relevant IP protection
- Not retrospective - applicable only to local IP commercialisation occurring after announced start date.

Australia's Loss is a gain to Peer Nations

Australia's high corporate tax rates and the absence of any compensating incentive has led to a significant diminishment of Australian pharmaceutical, medical technology and biotechnology manufacturing capacity.

Over the past 25 years, facilities have progressively shutdown and plans for new ventures have been shelved as multinational (and Australian) companies chose to make their long-

term capital investments in other places. Like Australia, these countries offer highly skilled and paid workforces, world class academic institutions and high living standards but have materially lower corporate tax rates.

Companies do this because lower tax rates mean they can offer more competitive product pricing and more sustainable production.

The COVID19 crisis has highlighted the practical impact of this but the financial impact has not been quantified. At a minimum it includes direct employment, indirect employment, local, state and federal tax revenue (payroll tax, corporate tax, export revenue), and supply chain expenditure.

Ventilators - Australia was dependent on ResMed for locally manufactured ventilators. Originally an Australian company, ResMed moved their headquarters to the United States in 1990 and have been very outspoken that future production expansions would be in Singapore rather than in Australia or the US because of its taxation and business environment.

Vaccine - Australia's only option for onshore manufacture of a COVID19 vaccine is CSL's recombinant manufacturing facility in Melbourne. This facility was opened in 2014 for clinical phase manufacture but CSL announced in 2015 it would be building the much larger industrial scale manufacturing facility in Switzerland for business environment reasons which included tax. CSL's Chief Financial Officer said at the time "if Australia had a tax scheme similar to the United Kingdom's "patent box" regime, it would have made the decision to overlook CSL's original home more difficult".

Further, there are many examples of significant investment in advanced manufacturing infrastructure and jobs creation in jurisdictions offering commercialisation incentives and withdrawal from Australia. Some notable examples include:

GlaxoSmithKline - In a 2010 press release entitled "Government patent box proposals 'transform' UK attractiveness for investment", GlaxoSmithKline announced the local manufacture of next generation respiratory inhalation devices and the construction of their new biopharmaceutical manufacturing plant. Together, these represented an investment of £500 million and the creation of 1,000 new jobs (in addition to those in the wider construction industry). The CEO said "For too long, while great inventions and discoveries have been made in the UK, downstream economic activity in development and manufacturing, and associated employment, have been attracted to other countries which have , more favourable corporation tax regimes. In one stroke, the introduction of the UK patent box will help change this dynamic".[vi]

Subsequently, on 22 October 2020, GSK has announced the permanent closure of their Boronia, Victoria blow-fill-seal plant which has operated continuously for 50 years. This will cost 300 direct jobs[vii] and many more in the Victorian supply chain for medical manufacturers.

Pfizer – In 2018, announced it was expanding its gene therapy manufacturing facility at Sanford campus in North Carolina, US. "The company is investing $500m in the project, which is in addition to $100m invested in August 2017 for facility expansion. The new investment forms part of Pfizer's $5bn planned investment in its US capital projects over the next few years."viii

Subsequently, on 20 October 2020, Pfizer's decision to close it's Bentley, Perth plant will cost 470 direct jobs plus those in its supply chain. Pfizer's facility used to manufacture oncology pharmaceuticals for export to North America, Europe, Africa, Latin American, Asia and Chinaix. It follows the announcement in September 2020, that it was selling its Adelaide manufacturing facility.

Cochlear - In June 2019, Australian medical technology company Cochlear announced it would commence manufacturing cochlear implant sound processors at its Global Repair Centre site in Kuala Lumpur, Malaysia. This was the first time Cochlear sound processors had been manufactured outside Australia. Cochlear's Senior Vice President Supply Chain and Operational Excellence said "Kuala Lumpur has proven to be a great place to centralise our global support services…The legal and regulatory environment is pro-business, tax rules are attractive and English-language skills are abundant…Malaysia is and will increasingly be an important part of our global operations network."

4.0 A Plea to the Australian Government

Maintaining some of the world's highest corporate tax rates make Australia an unattractive environment for the commercialisation of medical research compared to the UK, US, Switzerland, France, Singapore etc. Grants schemes alone cannot possibly mitigate this impact for manufacturers seeking to initiate or grow export markets.
An MMI would be consistent with the Government's stated objectives of supporting local advanced manufacturing and capability in relation to critical medical and biotech products.

The introduction of an MMI would mitigate (for medical manufacturing based on Australian R&D) the disadvantage of Australia's high corporate tax rate comparative to other OECD nations.

Whilst the taxation rate suggested is substantially lower than the current Australian corporate tax rate, the Government would be collecting revenue and other benefits from activity that will not occur onshore without such a policy.

The introduction of the MMI would help counter the current international mobility of

intellectual property and loss of long-term tax revenue.

IP tax incentives only apply to successful, revenue generating, innovations and therefore the MMI would provide a very targeted approach for on-shoring the commercialisation of medical and biotech research.

IP tax incentives provide revenue prospects for those governments, such as Australia, who provide large investments in front ended measures such as R&D incentives. R&D inherently entails high rates of failure. As a result, where R&D has succeeded, IP tax incentives provide a mechanism for governments to recoupment their investment by incentivising local commercialisation.

The measure of this benefit is not just tax revenue, but also driving productivity, creating jobs, developing a more highly skilled workforce and the creation of associated supply chains required to commercially deploy the innovation.

5.0 Further Information

Members of the Australian Medical Manufacturing Exporters Coalition would be pleased to provide further information or participate in consultations.

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[i] https://au.gsk.com/en-au/media/press-releases/2020/following-decision-announced-in-july-gsk-confirms-boronia-manufacturing-site-to-close-at-end-of-2022/
[ii] https://www.abc.net.au/radio/perth/programs/drive/pfizer-to-close-perth-factory/12795770
[iii] Australia ranks in the top 10 nations for human capital and research on the Global Innovation Index https://www.wipo.int/global_innovation_index/en/2020/

[iv] https://www.industry.gov.au/sites/default/files/October%202020/document/make-it-happen-modern-manufacturing-strategy.pdf
[v] https://www.wipo.int/global_innovation_index/en/2020/

[vi] https://www.gsk.com/en-gb/media/press-releases/government-patent-box-proposals-transform-uk-attractiveness-for-investment/
[vii] https://au.gsk.com/en-au/media/press-releases/2020/following-decision-announced-in-july-gsk-confirms-boronia-manufacturing-site-to-close-at-end-of-2022/
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