Medicines Australia | Better health through research and innovation

14 September 2021

Senate Standing Committee on Economics
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Committee Members,

Re. Submission from Medicines Australia on Australian manufacturing

Thank you for the opportunity to respond to this inquiry.

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

The COVID-19 pandemic has reinforced the link between Australia's health and economic wealth, and the value of investment in health innovation and manufacturing. Australian biopharmaceutical manufacturing is inextricably linked to and reliant on the wider R&D ecosystem, including R&D incentives, reimbursement processes, the regulatory landscape, a skilled workforce and a strong Intellectual Property (IP) regime. In this submission, we highlight the key policies which will enable the Australian research-based medicines industry to play its part in creating greater employment opportunities, better health outcomes and a more competitive economy.

To discuss these issues further, please contact [redacted] (Head of Government Relations, [redacted].

Yours sincerely,

[redacted]

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CEO
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September 2021

Medicines Australia submission

Medicines Australia submission to the Senate Standing Committee on Economics inquiry on the Australian manufacturing industry

Medicines Australia

1. Introduction

Medicines Australia welcomes the opportunity to respond to the Committee's timely inquiry on Australian manufacturing. The COVID-19 pandemic has clearly demonstrated the link between Australia's health and economic wealth and the value of investment in health innovation.

With the right policies in place, the Australian research-based medicines industry can play its part in creating greater employment opportunities, better health outcomes and a more competitive economy. This will place Australia at the forefront of advancements in medicine, digital health, artificial intelligence, 3D printing, nanotechnology and biologics. Australian biopharmaceutical manufacturing is inextricably linked to and reliant on the wider R&D ecosystem, including R&D incentives, reimbursement processes, the regulatory landscape, a skilled workforce and a strong Intellectual Property (IP) regime. As a result, the best way to reinvigorate economic growth and raise living standards is to support an ecosystem of partnerships that innovate, develop and manufacture innovative medicines, biopharmaceuticals and vaccines.

To build resilient supply chains, governments should focus on reducing trade barriers to enable the frictionless movement of pharmaceutical ingredients and components across borders. Medicines Australia has also consistently argued during the pandemic that the Australian Government should also leverage existing alliances such as the Five Eyes and defence allies to strengthen supply chain arrangements and provide mutual benefits in times of crisis of national and global significance. This is because pharmaceutical supply chains are global in nature, and it is not possible to relocate entire supply chains in any one country. Domestic manufacturing capability is important but must be part of a strong global supply chain.

Australia faces several comparative disadvantages in scaling up its manufacturing when competing with other countries. These include high labour and energy costs, and geographic distance to major global markets. It is therefore vital that the Government prioritises the right policies to build a more resilient medicines supply chain and provide globally competitive incentives for innovative companies to establish manufacturing sites in Australia.

There are several encouraging initiatives and reviews relating to the Australian research-based medicines industry, including the recent Strategic Agreement between the Federal Government and Medicines Australia,[1] the House of Representative Standing Committee on Health, Aged Care and Sport's inquiry into new drugs and novel medical technologies, and the Department of Health's review of the National Medicines Policy. Medicines Australia and our members welcome these measures, but

[1] Medicines Australia has secured a 5-year Strategic Agreement with the Federal Government, centred on earlier patient involvement and influence in the availability of new medicines in Australia. For more info, see: https://www.medicinesaustralia.com.au/policy/strategic-agreement-2022-2027/

for there to be productive outcomes, there also needs to be a coordinated approach across Federal and State Governments.

2. Summary of recommendations

For Australia to strengthen its medicines supply chains and attract more R&D investment, including biomanufacturing, the Government should:

- **National coordination:** Establish a high-level government-industry forum for Australia's pharmaceutical and biotechnology sectors to improve the coordination, consistency and collaboration across Australia to drive greater social, health and economic benefits.
- **Overall R&D ecosystem:** Improve medicines regulatory and Pharmaceutical Benefits Scheme (PBS) reimbursement processes to increase Australia's global competitiveness.
- **mRNA manufacturing:** Ensure mRNA manufacturing initiatives in Australian states are coordinated nationally to be globally competitive.
- **Regenerative medicine (RM):** Invest in Australia's sovereign manufacturing capability for complex and advanced RM therapies to secure access for Australian patients and benefits to the economy.
- **Supply chains:** Ensure that there is not further proliferation of supply chain focused government-industry forums with overlapping remits and forums are centrally coordinated.
- **R&D Tax Incentive (RDTI):** Partner with industry to review the impact of the revised RDTI on biopharmaceutical innovation, clinical trials and innovative manufacturing to identify where further changes are warranted.
- **Patent box:** Lower the proposed concessional tax rate of 17 per cent to ensure that the scheme succeeds in increasing the competitiveness of the Australian tax system for globally mobile innovative companies; and ensure the concessional tax rate should be applied to all R&D expenditure directly incurred by the Australian taxpayer, regardless of whether it is conducted in Australia or overseas, where there has been substantive expenditure on R&D in Australia.
- **Modern Manufacturing Initiative (MMI):** Ensure that the MMI is focused on industries of future growth, such as the biopharmaceutical industry.
- **Industry-specific investment programs:** Re-examine previously effective industry-specific programs, such as Factor F, Pharmaceutical Industry Investment Program (PIIP) and Pharmaceutical Partnerships Program (P3) to further upgrade manufacturing and strengthen supply chains to meet Australia's future pandemic needs and respond to other crises.
- **Clinical trials:** Work closely with State Governments and industry, through Medicines Australia and the R&D Taskforce (RDTF) to harmonise processes for faster and more efficient start-up of clinical trials.
- **Intellectual property (IP):** Ensure that Australia champions a strong, stable and reliable IP system both domestically and internationally.

- **Workforce:** Invest in and support a strong science, technology, engineering and mathematics (STEM) workforce, including by working with industry and education providers to better align training with industry needs.

3. Australian biopharmaceutical manufacturing and opportunities for growth

The Australian research-based medicines industry plays a vital role in the health of the Australian economy and its citizens. Medicines Australia's members alone contributed approximately $9 billion to the Australian economy in 2016-17; employ, directly and indirectly, over 23,000 Australians; invest over $1 billion into R&D annually to help as many as 33,000 Australians get early access to emerging therapies.[2] From 2009 to 2019, the value of pharmaceutical exports grew from $4 billion to $4.5 billion.[3] See Box 1 for two examples of global companies that are manufacturing innovative medicines in Australia. However, none of this value accounts for the additional and largely unquantified benefits to Australian patients' health, wellbeing and the significant economic spill-over effects.

As the COVID-19 crisis escalated in Australia, the industry acted swiftly and effectively to support governments, healthcare professionals, patients, and the scientific community on numerous levels. The industry has worked with Government, healthcare professionals and consumer organisations throughout the pandemic to maintain the supply of essential medicines and vaccines to the Australians who need them. We are committed to supporting Australia and Australians in these challenging times. Section 3 below discusses supply chains and trade disruptions in more detail.

Box 1: Case study on Novartis

In January 2020, *Novartis Global* announced an agreement with *Cell Therapies* to manufacture Kymriah®, at its production facility within the *Peter MacCallum Cancer Centre* in Melbourne. *Cell Therapies* is an Australia-based, globally active commercial contract development and manufacturing company, specialising in cell therapy, gene therapy, regenerative medicine, and cellular immunotherapy products.

Kymriah®, an innovative chimeric antigen receptor T cell (CAR-T) treatment, is approved by the Therapeutic Goods Administration (TGA) for use in Australia. It is an immunocellular therapy, a one-time treatment, manufactured individually for each patient using their own T cells, genetically reengineered and programmed to recognise and destroy cancer cells.

[2] Medicines Australia members survey
[3] Medicines Australia (2021), 'Medicines Australia Facts Book', Fifth Edition: https://www.medicinesaustralia.com.au/publications/facts-book/

Novartis is a pioneer in individualised medicine, making a bold early commitment to reimagine cancer care in the emerging field of CAR-T therapies.

The Cell Therapies manufacturing facility within the Peter MacCallum Cancer Centre will be used to supply patients with Kymriah in Australia and across the world. In late 2020, Novartis transferred the innovative manufacturing technology for Kymriah to Cell Therapies, who now has the capability to manufacture locally.

Novartis acknowledges the Australian Government's $80 million investment to the Peter MacCallum Cancer Centre to create Australia's first Centre of Excellence in Cellular Immunotherapy which recognised the significant potential of CAR-T to revolutionise cancer treatment.

The pandemic has also escalated the importance of advanced biomanufacturing, such as mRNA technology. mRNA has not only created a new frontier for vaccine development, but also become a promising new weapon in the fight against cancer and other diseases. The Government is right to identify mRNA as a technology of the future and public investment in this area is welcome. However, Australia is not alone in recognising the promise of mRNA technology; many major countries are committing considerable public investment to support mRNA initiatives. While the mRNA initiatives in many different Australian states indicate the right vision for mRNA in Australia, these initiatives must be seen in the global context, and as such, must be coordinated if they are to be successful.

Regenerative medicine (RM)[4] is another high-growth field within the biopharmaceutical sector, and with the right investments, Australia has an opportunity to establish a strong sector. If Australia gets this right, its RM industry could be worth at least $6 billion in annual revenue, 6,000 new jobs for Australia by 2035, and enable earlier access to ground-breaking therapies for Australian patients.[5]

RM therapies require highly specialised GMP capabilities and infrastructure, a highly skilled workforce, and complex supply chains. More than 40 companies in Australia are developing RM products and more than 65 clinical trials are in progress. Australia has seven TGA-licenced Good Manufacturing Practice (GMP) sites and five non-TGA licenced sites,[6] which are spread across

[4] Regenerative medicine is a multidisciplinary field that seeks to develop the science and tools that can help repair, augment, replace, or regenerate damaged or diseased human cells, tissues, genes, organs, or metabolic processes, to restore normal function. It may involve the transplantation of stem cells, progenitor cells, or tissue, stimulation of the body's own repair mechanisms, or the use of cells as delivery vehicles for therapeutic agents such as genes and cytokines.

[5] Regenerative Medicine Catalyst Project (2021), 'Australia's Regenerative Medicine Manufacturing Capacity & Capability': https://www.ausbiotech.org/documents/item/666

[6] Being TGA-licenced means that the manufacturing facility and quality systems have been approved by the local regulatory authority and products manufactured by these facilities meet global regulatory standards such as US (FDA), Europe (EMA), Japan and other jurisdictions. Those sites not yet TGA licenced are aspiring to be, so that they can extend their manufacturing capability to late-stage clinical trials and commercial supply.

several states. The increasing demand for RM therapy manufacturers is growing and a major bottleneck exists at the GMP manufacturing phase of product development, both in Australia and globally. Investing in and building Australia's sovereign manufacturing capability for complex and advanced RM therapies will ensure faster access to cutting-edge treatments for Australian patients, create new jobs now and for the future, and develop a highly skilled workforce.

4. Pharmaceutical supply chains

Pharmaceutical supply chains are complex and global in nature. Throughout the pandemic, the industry has worked hard to ensure the supply of essential medicines to patients, and to build strong international supply chains to manufacture and supply COVID-19 vaccines. The Pfizer/ BioNTech vaccine contains 280 different ingredients sourced from 86 suppliers located in 19 countries. The supply chains for the Oxford/AstraZeneca and Moderna vaccines are similarly complex.[7] As it is not possible to relocate entire supply chains in any one country, governments should focus on reducing trade barriers to enable the frictionless movement of pharmaceutical ingredients and components across borders.

Compared to many other countries, Australia faces several disadvantages in scaling up its manufacturing, including high labour and energy costs, and geographic distance to major global markets[8]. For Australia to build a more resilient medicines supply chain, we must be a trusted partner in a globally interconnected research-driven pharmaceutical industry.

The Productivity Commission's report into Vulnerable Supply Chains states:

> *One area where government could focus its efforts is on ensuring that firms do not face unnecessary constraints on how they plan for and respond to disruptions. A trusted and rules-based trading environment, for example, facilitates firms' ability to diversify their suppliers in preparation for, and their ability to find alternative suppliers in response to, a supply chain disruption. A responsive regulatory environment is another example*.[9]

A key aspect in responding to supply chain threats during the COVID-19 outbreak was a collaborative and flexible approach between Government, the Therapeutic Goods Administration (TGA) and the medicines industry. As a result of these efforts, there was not a significant disruption to the

[7] International Federation of Pharmaceutical Manufacturers & Associations (2021), 'Challenges and solutions to scaling-up COVID-19 vaccine manufacturing capacity': https://www.ifpma.org/global-health-matters/challenges-and-solutions-to-scaling-up-covid-19-vaccine-manufacturing-capacity/
[8] MTPConnect (2020), Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan, p28: https://www.mtpconnect.org.au/images/2020%20MTPConnect%20Sector%20Competitiveness%20Plan.pdf
[9] Productivity Commission (2021), Vulnerable Supply Chains, Study Report, July, p.8: https://www.pc.gov.au/inquiries/completed/supply-chains/report/supply-chains.docx

medicines supply chain, meaning that patients in Australia and around the world have continued to have access to essential medicines during the pandemic. Onshoring manufacturing is a solution for products with less complexity; however, for more complex products, regulatory flexibility is required, particularly during supply disruptions.

The Government has formed numerous working groups and other initiatives to monitor and manage supply chain disruptions with industry. Examples of these groups and initiatives include: the Medicines Shortages Working Party, convened by the TGA and attended by industry bodies; Department of Industry, Science, Energy and Resources (DISER) Supply Chain Roundtables, attended by cross-industry peak bodies; the newly established Office of Supply Chain Resilience (OSCR), part of the Department of the Prime Minister and Cabinet; DMTC's National Health Security Resilience Assessment, which seeks to survey Australia's capability and capacity for R&D, manufacturing, supply chain resilience and distribution of priority products and solutions that contribute to national health security; the Treasury's Business Liaison Unit, which convenes regular meetings with industry bodies; and the Department of Foreign Affairs and Trade (DFAT), which also convenes regular meetings with industry bodies. While the Government's attention to the importance of supply chains is welcome, there has been a proliferation of government-industry forums with overlapping remits. For these forums to be productive, they should be consolidated and centrally coordinated.

5. Government measures to attract R&D investment

The Government has a key role to provide a stable and competitive business environment for innovative companies, and to incentivise global companies to invest in R&D in Australia, including by establishing Australian manufacturing sites as part of their global supply chains. This section highlights important government measures to attract R&D investment.

a. R&D Tax Incentive

The R&D Tax Incentive (RDTI), which offers tax offsets for eligible R&D expenditure, is a critical component of Australia's attractiveness to global investment. We recommend that the Government works with industry to review the impact of the revised RDTI on pharmaceutical innovation, clinical trials and innovative manufacturing to identify where further changes are warranted.

b. Patent box scheme

Medicines Australia welcomes the Government's decision to implement an Australian patent box scheme. The scheme, currently under consultation by the Treasury, will offer concessional tax treatment to profits derived from eligible intellectual property (IP). A patent box is a step in the right direction to incentivise innovative pharmaceutical and biotech companies to commercialise IP in Australia and will boost Australian biopharmaceutical manufacturing.

The Government's proposed concessional tax rate of 17 per cent is well above global equivalents. For example, the concessional tax rate under the patent box in the United Kingdom is 10 per cent. As the policy aim of the Government is to "encourage companies to base their medical and biotechnology R&D operations, and commercialise innovation, in Australia and to retain associated patent profits in Australia",[10] the concessional tax rate must be viewed in a global context. For the patent box to be effective in increasing the competitiveness of the Australian tax system for globally mobile innovative companies, the proposed concessional tax rate of 17 per cent must be lowered.

In addition, Medicines Australia recommends the concessional tax rate should be applied to all R&D expenditure directly incurred by the Australian taxpayer, regardless of whether it is conducted in Australia or overseas, where there has been substantive expenditure on R&D in Australia.

c. Industry-specific investment programs

The Modern Manufacturing Initiative (MMI) is a $1.3 billion program under the Government's Modern Manufacturing Strategy. MMI seeks to encourage private investment by investing in large transformative projects and enabling collaboration. It is welcome that one of MMI's six focus areas is medical products.

In addition to the MMI, the Government could re-examine previously effective industry-specific programs, such as Factor F, Pharmaceutical Industry Investment Program (PIIP) and Pharmaceutical Partnerships Program (P3), to further upgrade manufacturing and strengthen supply chains to meet Australia's future pandemic needs and respond to other crises.

d. Clinical trials

If Federal and State Governments work closely together to harmonise processes for faster and more efficient start-up of trials, then Medicines Australia members and other research- based organisations will be better equipped to attract clinical trials and investment into Australia. We recommend that Federal and State Governments work together with industry, through Medicines Australia and the Research and Development Taskforce (RDTF), to:

- Promote domestically and internationally that Australia is open for business to conduct clinical trials
- Embed clinical trials as part of the standard treatment of care in the national health infrastructure, including regionally through clinical tele-trials
- Harmonise ethics, governance and regulatory processes nationally for consistently faster and more efficient establishment of clinical trials across Australia, building on the proposed Front Door initiative and work underway through the Australian Commission on Safety and Quality in Health Care

[10] https://treasury.gov.au/consultation/c2021-177849

- Strengthen the capacity to conduct clinical tele-trials in rural, remote and regional areas
- Develop nationally agreed clinical trials standards and guidance on:
    - tele-health
    - tele-trials
    - remote monitoring (including delivery and management of Investigational Medicinal Product)
    - the utilisation of digital technology, such as access to electronic Medical Records (eMR), e-signatures and e-consent
- Retain for the future, the more efficient changes to ethics, governance and regulatory measures implemented under COVID-19

e. Championing a strong IP system domestically and internationally

A strong, stable and reliable intellectual property (IP) and patent system is essential in supporting investment in new research for some of our most challenging diseases. Australia has a generally strong reputation on IP, however, maintaining a stable and reliable IP regime that is aligned with international best practice is critical to Australia's competitiveness in attracting foreign investment. Australia's patent system, administered through IP Australia, aims to encourage future research and development that delivers value to the economy and the community. In addition, it is the well accepted right of the IP holder to defend and protect their intellectual property, as the discoverer and/or inventor of the innovation. The promotion and protection of IP spurs further economic growth; creates new jobs and industries; and enhances quality of life.

Some individuals, organisations, and governments – including the Biden Administration – have called for the suspension of IP protections to improve access to COVID-19 vaccines, including compulsory licensing via a patent waiver of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While Medicines Australia, together with global life sciences associations and the biopharmaceutical industry, are fully aligned with the goal to ensure COVID-19 vaccines are quickly and equitably shared around the world, the proposed TRIPS waiver will not increase vaccine production nor increase the rate of vaccination in poorer countries.

The innovative biopharmaceutical industry has rapidly developed safe and effective vaccines thanks to its scientific expertise, its willingness to take financial risks, and a strong framework for the protection of IP. Safe, effective vaccines and ongoing R&D in response to emerging variants require robust partnerships that need to be supported by the international IP system. Undermining this system via the TRIPS waiver would only hinder the global vaccination effort. Instead, to achieve a high vaccination rate globally, we must have the right mechanisms in place to scale-up research, development, manufacturing, and supply of such products in our fight against COVID-19. Medicines Australia and our members are committed to working in collaboration with all stakeholders to find

solutions to tackle this pandemic. The Australian Government should work with industry to champion a strong, stable and reliable IP system both domestically and internationally.

Whether unilaterally or through multilateral FTAs, Australia should align its IP regime with key trading partners to boost Australia's competitiveness and strengthen its reputation. The more Australia is aligned with other countries, the more effectively it will compete in the global race for investments in R&D, biotechnology and commercialisation of innovative medicines. There is an opportunity in the current environment in Australia to strengthen the IP system to better align with other jurisdictions. The current system of five years' data exclusivity and an average 12 years of effective patent life are less attractive than comparable innovation and investment driven systems in other OECD countries with whom we compete.

Beyond strong IP chapters in FTAs, the Government should include pharmaceutical chapters in FTAs. The inclusion of a set of mutually agreed principles that recognise the significant role that the innovative pharmaceutical industry has in delivering high quality healthcare is essential in providing the foundation for a successful FTA.

f. Building a skilled workforce

The Australian biopharmaceutical industry relies on science, technology, engineering and mathematics (STEM) qualified employees to drive R&D, including advanced manufacturing. Medicines Australia recommends that the Government implements the following measures to boost our future competitiveness and help create high-skill jobs:

- Support further investment in the innovative medicines sector to continue to drive the demand for high-skills jobs
- Ensure that Australia has a suitably skilled and adaptable workforce to supply people qualified in STEM
- Reduce employment barriers through initiatives targeted (but not limited to) people of Aboriginal and Torres Strait Islander backgrounds, people with a disability, women, and people from diverse cultural backgrounds
- Work with the medicines industry and the education, training and research system to better align training with industry needs
- Ensure that the Australian visa system enables companies and research institute to effortlessly secure working visas for all levels of researchers and essential colleagues with unique manufacturing expertise

About Medicines Australia

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members develop, manufacture and supply critical medicines and vaccines available on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP). Our membership comprises small, medium and large Australian and multi-national companies. Many of the world's multi-national medicines manufacturers are members of Medicines Australia through their local affiliates. These local affiliates provide a critical worldwide connection that enables Australians to access globally developed breakthrough medicines and therapies.

The COVID-19 pandemic has unquestionably established that Australia's overall health and economic indicators are inextricably linked. Medicines are an integral component of healthcare and assist Australians to live longer and healthier lives, remain productive and employed, avoid hospitalisation, and positively participate in, and contribute to, the community and the economy. Every innovative medicine made available in Australia generates a significant return on investment to the patient, the community, the economy, and the Government.

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