



Senator the Hon David Fawcett
Joint Standing Committee on Foreign Affairs, Defence and Trade
PO Box 6021
Parliament House
Canberra ACT 2600

29 June 2020

Dear Senator Fawcett,

'Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade'.

Thank you to the Joint Standing Committee on Foreign Affairs, Defence and Trade for the opportunity to provide a submission to the 'Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade'.

Medicines Australia is the peak industry body representing the innovative research-based medicines industry in Australia. Our members are innovative companies that research, develop, manufacture and supply new medicines, therapies and vaccines to the Australian market. The innovative medicines industry is proud of the contribution it makes to the health and well-being of everyday Australians, as well as to the local economy.

Medicines Australia's members already play a vital role in the health of the Australian economy and its citizens. Our members contributed approximately \$10 billion to the Australian economy in 2018; employ, directly and indirectly, over 23,000 Australians; invest over \$1 billion into research and development annually to help 33,000 Australians get early access to emerging therapies. In 2019, there were 1,820 ongoing trials in Australia: a 22% increase on 2015. In 2017-18, our industry exported \$1.6 billion worth of medicinal products (rising to nearly \$4 billion if medicaments are included). None of this, of course, accounts for the additional and largely unquantified benefits to Australian patients' health, wellbeing and the significant economic spill-over effects.

Australia plays a growing role in a global pharmaceutical network that is a complex ecosystem of research and development partnerships that discover and manufacture medicines. The global pharmaceutical is a supportive network that, in the face of COVID-19, stood up very well. Governments, including supporting regulatory agencies, have come together and strengthened research collaboration, increased production and continue to trade in health-related products to the best of their abilities. Disruptions to the supply chain were primarily experienced due to restricted airfreight options as the majority of medicines are imported into Australia on passenger planes.

Any concerns about disruptions (strategic or otherwise) to the production of active pharmaceutical ingredients and subsequent medicines in China and India were largely unfounded. China's production volumes returned as soon as they were able, while India's restrictions on exports of certain medicines were short-lived and diplomatic efforts proved valuable to mitigate specific issues as they arose, such as country bans on exports of certain products. That said, the global diversification of these sorts of production lines also assisted to mitigate major supply disruptions.

The pandemic has seen our sector work closely with the Australian Government on a range of issues, particularly supply chain issues and patient access issues.

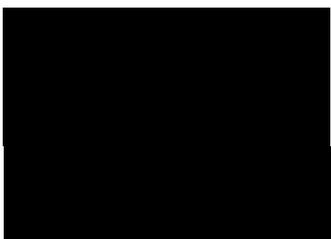
The pandemic has also highlighted some key opportunities which will be critical in the recovery of the Australian economy, for example positioning Australia as a global clinical research and development centre of excellence.

Now is the time to reignite Australia's ambition and capabilities in health and medical advancement by fostering collaborative partnerships in a health ecosystem that supports innovation, development and manufacture of high quality/high tech biopharmaceuticals and vaccines.

Medicines Australia would welcome the opportunity to appear before the Committee to discuss the strategic importance of our industry, the critical role which our sector has played during the COVID-19 pandemic and the significant contribution it will make in rebuilding an innovative and resilient economy.

For further information, please do not hesitate to contact me or Peter Komocki (Manager, Industry and Regulatory Policy).

Yours sincerely,



Medicines Australia

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Submission

Introduction

The COVID-19 pandemic has shown that a global problem needs a global solution. The innovative pharmaceutical industry is a global one, with the goal of developing and delivering novel medical treatments to all patients. One of the Australian pharmaceutical industry's roles during the pandemic has been to contribute to international research and development efforts in developing diagnostics, treatments and vaccines. Our industry's goal as we hope to move beyond COVID-19 is to continue providing innovative medicines to Australians, and to grow Australia's economy by providing jobs in research and development, commercialisation, advanced manufacturing and exports.

The strategic pathway forward for Australia, therefore, should be to strengthen our role in the international research, development and supply ecosystem, so that in a crisis such as this one, countries know that Australia is a reliable and trusted partner.

Medicines Australia is the peak industry body representing the innovative research-based medicines industry in Australia that is working tirelessly to develop COVID-19 treatments and vaccines. Our members are innovative companies that research, develop, manufacture and supply new medicines, therapies and vaccines to the Australian market. Our members proud of the contribution they make to the health and well-being of everyday Australians, as well as to the local economy.

Medicines Australia's members play a vital role in the health of the Australian economy and its citizens. Our members contributed approximately \$10 billion to the Australian economy in 2018 employ, directly and indirectly, over 23,000 Australians; invest over \$1 billion into research and development annually to help 33,000 Australians get early access to emerging therapies. In 2019, there were 1,820 ongoing trials in Australia: a 22% increase on 2015. In 2017-18, our industry exported \$1.6 billion worth of medicinal products (rising to nearly \$4 billion if medicaments are included). None of this, of course, accounts for the additional and largely unquantified benefits to Australian patients' health, wellbeing, and the significant economic spill-over effects.

Summary of Recommendations

Recommendation: *That the Australian Government strengthen strategic regional and global cooperation and trade for health-related products and services. This will provide research and development opportunities in Australia and secure multiple sources of medicines supply so that all Australians have access to world-leading and affordable treatments they need, when they need them. This includes strengthening strategic partnerships with our close neighbours in the Pacific and Asia-Pacific.*

Recommendation: *That the Australia Government take a leadership role to promote and strengthen the global rules-based order, including seeking for health-related trade and supply chains to have a special legal status in times of crisis to ensure patient needs are met. Australia should advocate for greater international recognition that the global rules-based order stood up to the task of helping manage a global response to a global problem.*

Recommendation: *The Australian government investigate various forms of international health-related agreements to secure stronger and more diversified supply chains, including through:*

- *Sector specific regional, plurilateral and multilateral agreements covering health-related research and development, manufacturing, trade and investment, and international green lanes*
- *Updating and harmonising older FTAs to align and simplify trade*
 - *Updates could include securing safer supply chains for medicines.*
- *Security of supply agreements with strategic partners*
- *Regional stockpiling agreements, particularly in the Pacific and Indo-Pacific between Governments and industry*

Recommendation: *A resilient national framework that allows Australia to achieve its economic and strategic objectives should involve supporting Australia's regional leadership role in global pharmaceutical development. To achieve this, the Australian Government must focus on an innovation-based economy by encouraging an ecosystem of medical research and development partnerships that translate discoveries into commercial products, increase supply chain efficiencies and open the door to more advanced manufacturing.*

The International strategic context and the global rules-based order

Recommendation: *That the Australian Government strengthen strategic regional and global cooperation and trade for health-related products and services. This will provide research and development opportunities in Australia and secure multiple sources of medicines supply so that all Australians have access to world-leading and affordable treatments they need, when they need them. This includes strengthening strategic partnerships with our close neighbours in the Pacific and Asia-Pacific.*

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From the innovative pharmaceutical industry perspective, the COVID-19 pandemic has shown that a global health problem requires a global response. It must be highlighted, however, that this is consistent with industry's approach to curing and treating all diseases. In the COVID-19 context, this approach became acutely visible. Governments, including supporting regulatory agencies, have come together with industry to assist and support each other domestically, regionally and globally, while also committing to keep supply chains connected and open.¹ This is in recognition that the development and supply of medicines is a global project and that medicines are meant for all.

The development, production and distribution supply chains are global and cannot be simply unwound to meet traditional strategic foreign policy alliance objectives. For example, while China might make the majority of the world's active pharmaceutical ingredients (APIs) that go into making many medicines, it is still heavily reliant on other countries for the importation of the finished products. India, on the other hand, is reliant on China's APIs to manufacture many of these medicines.

In responding to the COVID-19 pandemic, which includes the manufacture and distribution of medicines from a global network, our industry has seen the critical importance and reliance upon the global rules-based order. In short, the global rules-based order has worked and held up well, including in Australia which, we must always remember, is located far away from the main centres of manufacture.

To date, we have seen few incidences of protectionism, showing that in times of crisis the global order can be relied upon. A global problem did indeed deliver a global response, which existing global rules facilitated. The Australian Government, recognising that we cannot be entirely self-sufficient in respect of medicines, should take a leadership role in promoting these successes and further strengthen internationally, including through the World Trade Organization, United Nations and the Asia Pacific Economic Cooperation forum, the opportunities for countries to cooperate in the development, manufacture and supply of pharmaceutical products.

¹ See for example <https://www.dfat.gov.au/news/news/joint-ministerial-statement-australia-brunei-darussalam-canada-chile-republic-union-myanmar-new-zealand-and-singapore> and <https://www.dfat.gov.au/news/news/australia-japan-joint-ministerial-statement-response-covid-19-pandemic> and http://www.icmra.info/drupal/news/statement_on_COVID-19

A first and guiding principle could be that the pharmaceutical and health-related industries have a special legal status (akin to a diplomatic immunity) in times of crisis. The status could be similar to that of healthcare or the International Committee of the Red Cross/Crescent in humanitarian responses or conflict zones, particularly in terms of the development, manufacture and supply of medicines and medical services not being impeded. This could strengthen global supply chains and the capacity for all people to have access to medicines.

Secondly, supply chains could be further strengthened by better acknowledging the importance of pharmaceuticals in Australia's free trade agreements. The Australian Government could investigate additional strategic alliances with our existing partners to ensure the safe and equitable supply of medicines in times of crisis, including through important trade hubs like Singapore, direct trade routes from India and the US, and overland flights from the European Union.

Thirdly, closer to home, the Australian Government should continue to strengthen its strategic partnerships with our Pacific and Asia-Pacific neighbours. Under the right conditions, Australia could cement its role in the Pacific region as a partner of choice in securing supply chains for critical medicines, expanding beyond the traditional defence and foreign aid activities.

International Supply Chain Integrity and Security

Recommendation: *The Australian government investigate various forms of international health-related agreements to secure stronger and more diversified supply chains, including through:*

- *Sector specific regional, plurilateral and multilateral agreements covering health-related research and development, manufacturing, trade and investment, and international green lanes*
- *Updating and harmonising older FTAs to align and simplify trade*
 - *Updates could include securing safer supply chains for medicines.*
- *Security of supply agreements with strategic partners*
- *Regional stockpiling agreements, particularly in the Pacific and Indo-Pacific between Governments and industry*

On a global level, companies are carefully tracking and managing not only the delivery of their medicines to Australia but also, for those that manufacture, they are tracking and managing all the inputs required to continue manufacturing. Our manufacturing facilities around the world are open and continue to make millions of doses of medicines and vaccines every day. Strict measures are in place to ensure our teams and facilities are protected and able to maintain production.

Our companies, over decades, have carefully built robust global supply chains to ensure patients around the world have ongoing access to medicines. Over the years, our companies have invested significantly in the design and maintenance of manufacturing facilities and their quality systems. This ensures that medicines are produced safely and efficiently so that patients have access to them as soon as possible. Individual innovative biopharmaceutical companies have taken careful measures to ensure the stability of their supply chains.

Geographic diversity is key to the success of global supply chains, enabling manufacturers to quickly adjust, as needed, their supply chain sourcing, particularly during natural emergencies, crisis and global public health crises such as COVID-19. In developing their supply chains, manufacturers take into account the

locations of each source facility and have extensive measures in place to manage the various elements of the production process.

As noted already, supply chains of medical products were tested during COVID-19 and, in part due to the Australian Government's quick response in containing the outbreak, supply chains withstood additional demand. This did, however, require judicious and determined restraint from manufacturers and distributors in restricting the filling of medicines orders from state and territory hospitals and community pharmacies that were multiple times the usual norm. Industry cooperation, including with government, ensured that existing stock could continue to be sold and distributed while additional stock was ordered.

The main cause for concern in respect of supply resulted from the lockdowns of international passenger flights and airports. This is because the vast majority of pharmaceuticals and medical supplies are imported into Australia on passenger flights, particularly from Europe and the US. With fewer flights available, including cargo flights, the cost of freight increased exponentially. While this often made the import of medicines not commercially viable, our members continued to bring in products to meet Australian patient needs. It must be noted that Medicines Australia members did not pass on these additional costs to the government or patients. The Australian Government must also be commended for introducing the International Freight Assistance Mechanism, which prioritised cargo capacity for medical products on return legs to Australia.

We urge the Government to work with industry on what other mechanisms and safeguards are required as international passenger movements are expected to remain restricted. This could include strategic agreements for the airfreight of goods with Australia's closest trading partners to ensure cross-border flows of critical medicines and other products, in particular, the EU, UK, US, India and China.

To provide countries in the region with greater flexibility in managing potential supply restrictions, there is opportunity for the Australian Government to strengthen its relationships with Pacific and Indo-Pacific nations. In particular, the Australian Government should investigate creating regional stockpile agreements between governments and industry to ensure continued management and supply of medicines and medical products. This could include, for example, agreements with New Zealand, Pacific Nations, India, Indonesia, Malaysia, and Singapore.

In respect of Australia's international trade agenda, the Australian Government must continue to increase its levels of ambition when updating existing trade agreements, during the current negotiations and for the next generation of agreements.

There are many older and overlapping agreements that the Government should investigate reopening, updating and harmonising so as to reduce regulatory complexity.

In relation to the negotiations with the EU and upcoming ones with the UK, Medicines Australia has previously provided submissions on these issues and may provide additional input in the coming months so will not revisit those issues in detail here. Some issues relevant to free trade agreements and domestic policies are covered in section X below, including intellectual property and skilled migration.

Nonetheless, Medicines Australia supports the recommendations recently published by the Joint Standing Committee on Trade and Investment Growth in its report, "Trade transformation: *Supporting Australia's export and investment opportunities*". The report is the outcome of the Committee's 'Inquiry into Supporting Australia's Exports and Attracting Investment'. In particular:

Recommendation 11: The Committee recommends that the Australian Government continue to push for new export market opportunities, including by:

- the signing of new trade agreements, with a preference for multilateral and **regional** agreements where possible;
- considering options **to harmonise or streamline regulations** where Australia has overlapping trade agreements with the same country; and
- prioritising the needs of **small and medium sized businesses in** the context of trade negotiations.

*Recommendation 12: The Committee recommends that the Department of Foreign Affairs and Trade develop and **release a plan for boosting Australia's exports and investment once the vast majority of Australia's trade is covered by FTAs** (in line with the government's goal of achieving this by 2022).*

In relation to Recommendation 12, and in light of the COVID-19, Medicines Australia considers that now is the time for the Government to develop a renewed trade agenda in consultation with industry.

In order to strengthen strategic supply chains Australia must position itself as being a critical part of the research and development and subsequent supply ecosystem as a regional leader and strong global player. With 90% of Australia's trade soon to be covered by free trade agreements, Medicines Australia believes that the next logical step is for the Government to pursue sector specific agreements in bodies like the World Trade Organisation and the Asia Pacific Economic Forum, as well as through plurilateral agreements, both new or building on existing ones (such as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), Regional Comprehensive Economic Partnership (RCEP) and Australia, ASEAN, New Zealand Free Trade Agreement (AANZFTA)). These agreements should not only look at broadly eliminating tariffs but be aligned with the future needs of the industry in respect of

- research and development
- new treatments such as precision medicines and ones that harness pharmaceuticals, devices and services as part of standard of care
- intellectual property
- skilled migration
- regulatory harmonisation
- ensuring the safety and security of supply chains.

A resilient national framework to achieve Australia's economic and strategic objectives

Recommendation: *A resilient national framework that allows Australia to achieve its economic and strategic objectives should involve supporting Australia's regional leadership role in global pharmaceutical development. To achieve this, the Australian Government must focus on an innovation-based economy by encouraging an ecosystem of medical research and development partnerships that translate discoveries into commercial products, increase supply chain efficiencies and open the door to more advanced manufacturing.*

In seeking to play a greater strategic role in the global pharmaceutical space, while pulling Australia out of the economic difficulties that COVID-19 has wrought, Australia's opportunities lie in leveraging its competitive advantage in medical research and development. Cementing its role as a regional hub in the development of new innovative medicines and vaccines will strengthen Australia's hand in ensuring treatments reach patients who need them most.

Fostering an innovative environment will require more than the international initiatives outlined above, it will also require a domestic policy environment that attracts investment to Australia.

In the short, medium and long term, the best way to stimulate economic growth and higher incomes through the health sector is by encouraging an ecosystem of partnerships that innovate, develop and manufacture high-quality/high-tech biopharmaceuticals and vaccines. This will place Australia at the forefront of advancements in medicines (e.g. the rapidly emerging areas of precision cell and gene therapies – see attachment A), artificial intelligence, 3D printing, nanotechnology and biologics.

This will require a raft of policies and initiatives to strengthen the pipeline of partnerships that bring about innovation in Australia. Such policies should:

- facilitate public-private partnerships across other portfolios, including Defence (e.g. health and defence medical countermeasures initiative), to co-fund domestically focussed health security measures and pandemic preparedness
- incentivise and recognise Australian discoveries and development
- strengthen targeted research and development tax incentives for home-grown and manufactured products, and provide price premiums and expedited PBS listing for home-grown and manufactured medicines
- introduce collaboration premium (tax) incentives in the research and development space
- embed clinical trials into the core healthcare infrastructure, including in regional areas, as part of the standard treatment of care with costs co-covered by Medicare and study sponsors
- focus investment in STEM education, higher skills development and supporting skilled migration for identified gaps in scientific and senior managerial positions
- strengthen Intellectual property rights protections
- expand existing policy options such as, realigning the MRFF to
 - encourage and reward public-private collaboration
 - link with the EU Horizon fund to tap into international co-investment and collaboration opportunities
- promote translational centres of excellence for discoveries of Australian-made products
- focus on public-private manufacturing initiatives (i.e. through the CSIRO Innovation fund).

[Positioning Australia as a global research and development hub: re-opening for business to conduct trials/research](#)

For the pharmaceuticals industry in Australia, much of the research and development investment is focused on conducting clinical trials. In economic terms, total direct expenditure for ongoing clinical trials was estimated at \$1.1 billion in 2015. The majority of this funding is provided by innovator companies bringing in foreign direct investment (FDI). The estimated total expenditure supports approximately 6,900 highly skilled staff.² Australia has well developed and highly-regarded clinical trial facilities and medical infrastructure to conduct clinical trials in all phases of drug development. There are additional strengths in early phase (phase 1) capabilities.

Australia's successful management of the COVID-19 pandemic and reopening of our economy brings real opportunities to attract clinical trials here that would otherwise be done in the US, Spain, Italy and Germany or other countries severely affected by COVID-19.

² MTPConnect. Clinical Trials in Australia: The economic profile and competitive advantage of the Sector". June 2017

Global companies are looking to Australia and New Zealand as we effectively and rapidly limited the spread of COVID-19, while Europe and the US continue to struggle with increasing rates of infections. It highlights the unique position Australia is in to capture new business and build the sector further.

In bringing more of those trials here, we have the chance to grow Australia's clinical trial sector, the benefits of which include:

- elevated research and development capabilities
- closer international collaboration
- improvements to the healthcare system in metropolitan and rural areas
- clinical trials becoming imbedded in the health infrastructure's standard of care
- earlier access for Australian patients to the newest medicines
- more patients receive treatments
- will also improve our health-care system, strengthen research and development and improve patients' health outcomes.

The industry-led Research and Development Taskforce (RDTF) has outlined some of the additional steps that need to be taken for Australia to fully capitalise on its competitive advantage and the investment opportunities for the domestic clinical trials sector due to other nations' decreased capacity resulting from COVID-19.

Medicines Australia believes the Federal and State Governments should work together with industry, through Medicines Australia and the RDTF to:

1. Promote domestically and internationally that Australia is open for business to conduct clinical trials
2. Embed clinical trials as part of the standard treatment of care in the national health infrastructure, including regionally through clinical tele-trials
3. 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
4. Strengthen the capacity to conduct clinical tele-trials in rural, remote and regional areas
5. Develop nationally agreed clinical trials standards and guidance on
 - a. tele-health
 - b. tele-trials
 - c. remote monitoring (including delivery and management of Investigational Medicinal Product)
 - d. the utilisation of digital technology, such as access to electronic Medical Records (eMR), e-signatures and e-consent
6. Retain for the future, the more efficient changes to ethics, governance and regulatory measures implemented under COVID-19

The majority of the above could be achieved through agreement by the National Cabinet by end of mid-2021, including the development of national standards and guidance.

It is particularly important for the Federal and State Governments to work closely together to harmonise processes for faster and more efficient start-up of trials – ethics, governance and recruitment. Medicines Australia members and other research based organisations will then be better equipped to attract clinical trials and foreign direct investment into Australia. Each State should be commended for their interest and efforts to attract clinical trials at an individual State level. The key to taking advantage of this opportunity is to streamline and harmonise efforts across the States to harness efficiencies for multi-state and multi-site large clinical development programs, growing the national footprint in clinical trial and drug development pathways.

This priority has also been acknowledged in a recommendation of the Joint Standing Committee on Trade and Investment Growth's³ recent report:

Recommendation 3: The Committee recommends that the Australian Government, in collaboration with State and Territory Governments, the medical profession and pharmaceutical industry: develop a unified national regulatory scheme for the establishment, conduct and reporting of clinical trials in Australia.

Intellectual Property

Whether unilaterally or through international trade agreements, Australia should align its intellectual property protection 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 research, biotechnology and commercialisation of innovative medicines. There is an opportunity in the current environment in Australia to strengthen the intellectual property 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.

As such, it is imperative that Australia's laws better protect regulatory data, including clinical trial data. Innovative pharmaceutical companies rely upon this data to register medicines in Australia and to recoup their significant financial investment into the original research and development. This, in turn, is re-invested in future research and development products.

Current estimates for the cost of bringing an innovative pharmaceutical to market, including research and development, are up to \$2.6 billion over a 12-year period. If companies are unable to recoup at least a substantial part of these costs, future research and development activities and innovation is jeopardised and, by implication, so are the health outcomes of Australian patients.

In some instances, due to the time it takes to complete research and development activities and overcome various hurdles and setbacks in the research process, data exclusivity is the only period of protection available to innovator pharmaceutical companies that allows them recoup any of the costs they have spent bringing a product to market.

Medicines Australia urges the government to align its data exclusivity period, which is currently five years, with international best practice. Specifically, the European Union provides innovators with ten years of data exclusivity, which can be increased to eleven years for new uses with significant clinical benefit for patients. This comprises of eight years data exclusivity, followed by two years "market exclusivity" where a generic company can use the pre-clinical and clinical trial data of the originator in their regulatory applications, but still cannot market their product. This includes for orphan drugs, paediatric uses and areas of high unmet need (such as for new antimicrobial therapies).

In this light, Medicines Australia supports the recommendation of the Joint Standing Committee on Trade and Investment Growth's⁴ recent report:

Recommendation 3: The Committee recommends that the Australian Government, in collaboration with State and Territory Governments, the medical profession and pharmaceutical industry...review

³ "Trade transformation: *Supporting Australia's export and investment opportunities*". The report is the outcome of the Committee's 'Inquiry into Supporting Australia's Exports and Attracting Investment'.

⁴ "Trade transformation: *Supporting Australia's export and investment opportunities*". The report is the outcome of the Committee's 'Inquiry into Supporting Australia's Exports and Attracting Investment'.

Australia's intellectual property settings, particularly regulatory data protection and the patent notification scheme, to assess if they are an impediment to greater investment.

Commercialisation

It is an open secret that Australia is not as successful in translating research and developments in commercially viable products as other countries. Medicines Australia, and many of our members, proudly support The Bridge Program, which began in 2017 and selects 100 participants annually from across Australia to take part in face-to-face and online training in the various components that contribute to the commercialisation of new medicines.

The importance of this issue was highlighted in the very first recommendation of the Joint Standing Committee on Trade and Investment Growth's⁵ recent report:

*Recommendation 1: The Committee recommends that the Australian Government identify new and emerging trade opportunities and seek to apply the lessons learned from the **Biomedical Translation Fund** to help attract industry investment to those opportunities, as part of an updated trade and investment strategy.*

Medicines Australia supports this recommendation. However, more needs to be done across industry, the research and development sector and government.

In particular, the Australian Government (through the Department of Health in cooperation with the Department of Industry, Science, Energy and Resources) should work with industry and academia to review how commercialisation can be imbedded as part of the research and development culture in Australia. Collaboration will be vital to develop better commercialisation platforms that keep discoveries and their intellectual property in Australia. A culture that values public/private partnerships needs to be fostered, including through government research and development grants, tax incentives and the promotion of venture capital opportunities to fund and commercialise discoveries.

Research and Development Tax Incentive

Current research and development incentives provide significant support for businesses in the field to undertake, develop and extend their research and development activities that would otherwise not be possible or that would be significantly delayed or undertaken elsewhere.

In this regard, Medicines Australia believes the current tax incentive plays a major role in maintaining Australia's competitiveness as a preferred location for research and development activities.

These incentives also play a major role in maintaining Australia's international competitiveness as an important location for research and development, including crucial pre-clinical testing and early phase clinical trials, ensuring early access for patients to the latest medical developments.

It is commonly accepted that targeted Research and Development programs in advanced economies lead to greater productivity, jobs and growth.

⁵ "Trade transformation: *Supporting Australia's export and investment opportunities*". The report is the outcome of the Committee's 'Inquiry into Supporting Australia's Exports and Attracting Investment'.

Yet Australia has one of the lowest levels of support for research and development in the OECD. For a decade the nation's productivity has languished, while wages and economic growth have stagnated.⁶ The nation now faces the challenge of a sustained downturn in consumer confidence and business investment.

Medicines Australia continues to advocate for a strong, stable and predictable research and development tax incentive program that facilitates, rather than inhibits, the discovery of innovative biotherapeutics and vaccines, such as through:

- the return of a 45% refundable tax offset (an increase of 1.5%)
- introducing collaboration premiums (e.g. 20%) for research and development activities, for example, between companies and publicly-funded research institutes as non-refundable tax offsets
- opposing any introduction of tax off-set brackets based on the intensity of companies' research and development expenditure

Medicines Australia will maintain its advocacy for a streamlined system that clearly defines which activities are eligible, cuts red tape, promotes the integrity of research and development and limits misuse of the program for non- research and development activities.

This includes continuing to call for the current *Research and Development Tax Incentive Bill* before the Parliament to be withdrawn. Failing that, Medicines Australia calls for the biopharmaceutical and life sciences sector to be carved out of the scope of the Bill.

Advanced Manufacturing

Successful innovation is founded on a sustainable and growing ecosystem of partnerships for research and development and subsequent commercialisation. This opens advanced manufacturing and export opportunities.

Research and development is key; partnerships are essential.

Encouraging an ecosystem of partnerships that innovate, develop, and manufacture high-quality/high-tech biopharmaceuticals and vaccines should form a central component to a health led economic recovery. This may open the door to the possible niche bio-pharmaceutical manufacturing and other health related innovations, including medical devices and software, that support high value/highly skilled jobs.

With the right policies, we have the potential to upgrade manufacturing and strengthen supply chains to meet Australia's future strategic needs, including responding to future pandemics and other crises. This could include re-examining previously effective policies such as Factor F, Pharmaceutical Industry Investment Program (PIIP) and Pharmaceutical Partnerships Program (P3), alongside government co-investments, tax incentives, grants and loans.

The Australian Government, in partnership with the private sector, should urgently review Australia's current biopharmaceutical capacity and capability, identify gaps and establish which specific capabilities to focus on, such as vaccine manufacturing technology platforms. A comprehensive mapping exercise should build on the work already completed by the Department of Defence Science and Technology Medical Countermeasures Initiative in 2017. Policy options to enable capabilities can then be targeted to achieve the required investment.

⁶ www.globalinnovationindex.org/home

Developing Australia's Research, development and commercial skills

Australia's competitive advantages also lie in its people and their reputation for producing safe and high-quality biopharmaceutical products. Australia has a strong track record of extraordinary talent in science and technology who provide the foundations for quality niche and advanced manufacturing, and a first-class health and medical system.

Playing to these strengths provides opportunity to: further boost specialist workforces through education (e.g. STEM) and skilled migration; optimise our research and development excellence and capacity (academic research and clinical trials); embed translation of discoveries into real-world products; augment high-tech start-up and SMEs; increase niche manufacturing capacity and capability; and grow export opportunities.

The importance of this issue was also highlighted in the Joint Standing Committee on Trade and Investment Growth's⁷ recent report:

*Recommendation 5: The Committee recommends that the Australian Government, in consultation with industry, review the **Global Talent Employer Sponsored program** after one year to assess its effectiveness, and make amendments to the program if necessary.*

Medicines Australia supports this recommendation as we should be attracting global talent to Australia while educating and fostering our own.

Domestic Supply Chain Integrity and Security: Adopting critical health learnings and new efficiencies from the COVID-19 health response

An efficient domestic supply chain allows for closer monitoring and equitable distribution of medicines, particularly in time of crisis. Mitigating panic buying and stockpiling at the state and community pharmacy level ensures that medicines supply is better assured and importer and local manufacturers can manage supply orders more efficiently and provide more certainty that patients will have the medicines they need.

The focus on the supply chain has opened up opportunities to modernise and improve domestic supply chains and delivery methods. The response to COVID-19 has demonstrated that meaningful reform in supply chain funding and efficiencies can become possible within days not years.

The industry will seek to capture and maximize all new efficiencies in health management and delivery gathered from the COVID-19 crisis – including adopting remote telehealth capabilities and implementing virtual training.

Now is also the time to review critical COVID-19 learnings and introduce new visibility and efficiencies into the medicine supply chain supporting timely and reduced risk to patient care through track and trace capability (serialisation of medicine packs), electronic prescribing and direct delivery of medicines to patients. For example, different delivery methods provide value to patients and should be explored/maintained (eg direct delivery, e-Rx, Australia Post, Drones etc).

⁷ "Trade transformation: *Supporting Australia's export and investment opportunities*". The report is the outcome of the Committee's 'Inquiry into Supporting Australia's Exports and Attracting Investment'.

Medicines Australia recommends that the Federal Government foster the implementation of a modern technology enabled supply chain that ensures efficient resource utilisation and effective and timely delivery of medicines to Australian patients, through:

- i. Realising cost efficiencies through transparency of costs for each part of the supply chain
- ii. Implementing mechanisms to enable national visibility of stock management processes
- iii. Enhancing track and trace capability, including serialisation
- iv. Leveraging additional data streams to support healthcare system policy/decision-making
- v. Embedding the provision of direct delivery options for patients
- vi. Enabling and expanding data transfer of electronic prescribing.