28 May 2020

Senator Katy Gallagher, Chair

Senate Select Committee on COVID-19

Committee Secretary
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

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Dear Senator Gallagher,

SUBMISSION FROM MEDICINES AUSTRALIA

Thank you for the opportunity to provide a submission to the Senate Select Committee on COVID-19.

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.

Our members contributed approximately $9 billion to the Australian economy in 2016-17; they employ, directly and indirectly, around 23,000 Australians; and invest over $1 billion into research and development annually to help over 33,000 Australians get early access to emerging therapies. 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.

The COVID-19 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 centre of excellence.

Australia has a strong history in uncovering and developing significant advances in medical treatments from penicillin in the 1920s to Gardasil in the 1990s. A highly skilled scientific community, combined with strong research capabilities and a committed innovative pharmaceutical industry continues to place Australia on the global health stage for its health competency and substantial expertise.

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.

A renewed focus and investment in health innovation and advancement will not only place Australia even more firmly on the world stage, it will establish new benchmarks in health delivery that supports a stronger and healthier community while building a skilled health sector with higher wages and advanced infrastructure.

Ambition and action will build a simultaneous health led and wealth led economic recovery from the COVID-19 pandemic.

Medicines Australia would welcome the opportunity to appear before the Committee to discuss 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 on [redacted] or Jamie Snashall on [redacted]

Yours sincerely,

Elizabeth de Somer

CEO
Medicines Australia

SUBMISSION FROM MEDICINES AUSTRALIA TO THE SENATE SELECT COMMITTEE ON COVID-19

Executive Summary

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.

As the COVID-19 crisis escalated in Australia the innovative research-based medicines industry acted swiftly and effectively to support governments, healthcare professionals, patients, the scientific community and our employees on numerous levels. Our intent was (and is) to do whatever is required to support Australia through these challenging times.

Our focus has been to:

1. Deploy scientific expertise and capabilities in the fight against COVID-19 to uncover the urgently needed measures to protect and treat the community.
2. Maintain the supply of essential medicines and vaccines to patients who need them - in our hospitals and the community, by working collaboratively with Government, healthcare professionals and consumer organisations to manage and pre-empt healthcare delivery needs as they emerge.
3. Recognise and actively support Australia's healthcare professional community working on the frontline and the patients they serve.

As an industry, we recognise the critical role we must play, both in the urgent response to the COVID-19 crisis, but also in the recovery of Australia - ensuring our community manages their health effectively. We take this responsibility extremely seriously and with a strong conviction to succeed. COVID-19 has reinforced the importance and value of science and innovation – our core competencies. It has also generated new efficiencies and positive outcomes resulting from the rapid implementation of advancements in health delivery to healthcare professionals and patients (telehealth mechanisms, at home care, home delivery).

The nation's overall health and economic wealth have never been more clearly linked. Prioritising and investing in innovative and advanced health strategies, together with the scientific community, will help to build a purposeful economic recovery and future proof Australia. These important health-based recovery strategies include:

- Positioning Australia as a global clinical research centre of excellence opening up for business once again to conduct trials/research
- Committing to the timely introduction and broad access to innovative medicines and advancements in healthcare delivery
- Supporting a robust healthcare ecosystem that forms partnerships and collaborations to innovate, develop and manufacture high-quality/high-tech biopharmaceuticals and contributes to the delivery of high value jobs, highly skilled STEM-enabled workforce
- Adopting critical learnings and new efficiencies from the COVID-19 health response

It is important now to prioritise health not only to manage COVID-19 effectively but also to forge a future economic path for Australia. A strong trajectory in the advancement and evolution of healthcare delivery and maximisation of innovative medicines will be critical for success. Igniting a renewed 'health ambition' in Australia to step up to global benchmarks in science and innovation will place us in the strongest possible position to build a prosperous future.

Summary of Recommendations

The COVID-19 pandemic crisis has highlighted where there are gaps and challenges in our healthcare system and delivery. To 'future proof' Australia and continue to provide world class healthcare, we need to be fully prepared for any situation in the future, both short and long-term.

Short-term we need to be prepared for a second wave of COVID-19 infections and also for rapid implementation of clinical trials for COVID-19 vaccine(s) and treatment(s) to treat all Australians. For the long-term we need to be prepared for any unexpected pandemic or life-threatening situation to Australians, where healthcare is paramount, including other natural disasters such as bushfires, flood and drought.

Overall, the pandemic has demonstrated that implementation of healthcare strategies to ensure patient safety and reliable access to medicines is critical. These gains are important to retain. The following recommendations should be considered to 'future proof' Australia.

High Level Recommendation: (page 22)

That the Federal Government work with the private sector, through Medicines Australia, to review the current capacity of the sector and identify opportunities to enhance industry capabilities. Expanding Australia's contribution to the global innovative medicines industry, from discovery to patient access, would future proof the economy. Policy options to enable this capability building can then be targeted to achieve the required investment.

Detailed Recommendations:

Supply Chain: (page 24)

1. 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

2. That the Federal Government, for the purposes of national supply management:
    a. work with Medicines Australia to consider policy options to encourage greater supply chain redundancy and stock levels for identified/agreed products of clinical significance
    b. introduce national coordination of medicines supplies at all health levels including hospitals, States and Territories, to agree safe and equitable distribution during crisis
    c. ensure dispensing is appropriate to manage supplies at all times, but particularly during times of crisis
    d. ensure effective communication to consumers regarding stock shortages and stock-outs with advanced warning of stock shortages or stock-outs, rather than just a reliance on the TGA website and at pharmacy level
    e. establish a national mechanism to support patients in what they need to do to get access to medicines if there is a stock-out

Clinical trials: (page 18-19)

3. That Federal and State Governments work together with industry, through Medicines Australia and the Research and Development Taskforce (RDTF), to:
    a. Promote domestically and internationally that Australia is open for business to conduct clinical trials
    b. Embed clinical trials as part of the standard treatment of care in the national health infrastructure, including regionally through clinical tele-trials
    c. 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
    d. Strengthen the capacity to conduct clinical tele-trials in rural, remote and regional areas
    e. Develop nationally agreed clinical trials standards and guidance on
        i. tele-health
        ii. tele-trials
        iii. remote monitoring (including delivery and management of Investigational Medicinal Product)
        iv. the utilisation of digital technology, such as access to electronic Medical Records (eMR), e-signatures and e-consent
    f. 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 mid-2021, including the development of national standards and guidance.

Patient focus: (page 24)

4. That the Federal Government:
    a. Continue ongoing use of Telehealth, E-prescribing and Home Delivery of medicines beyond September, as an additional mechanism beyond face to face healthcare delivery.
    b. Incorporate the 'voice of the patient' in the matters of healthcare and utilise consumer expertise and expectations in policy decision making
    c. Promote the use of remote monitoring in clinical trials to ensure remote and rural patients have equal access compared to urban patients.

PBS: (page 20)

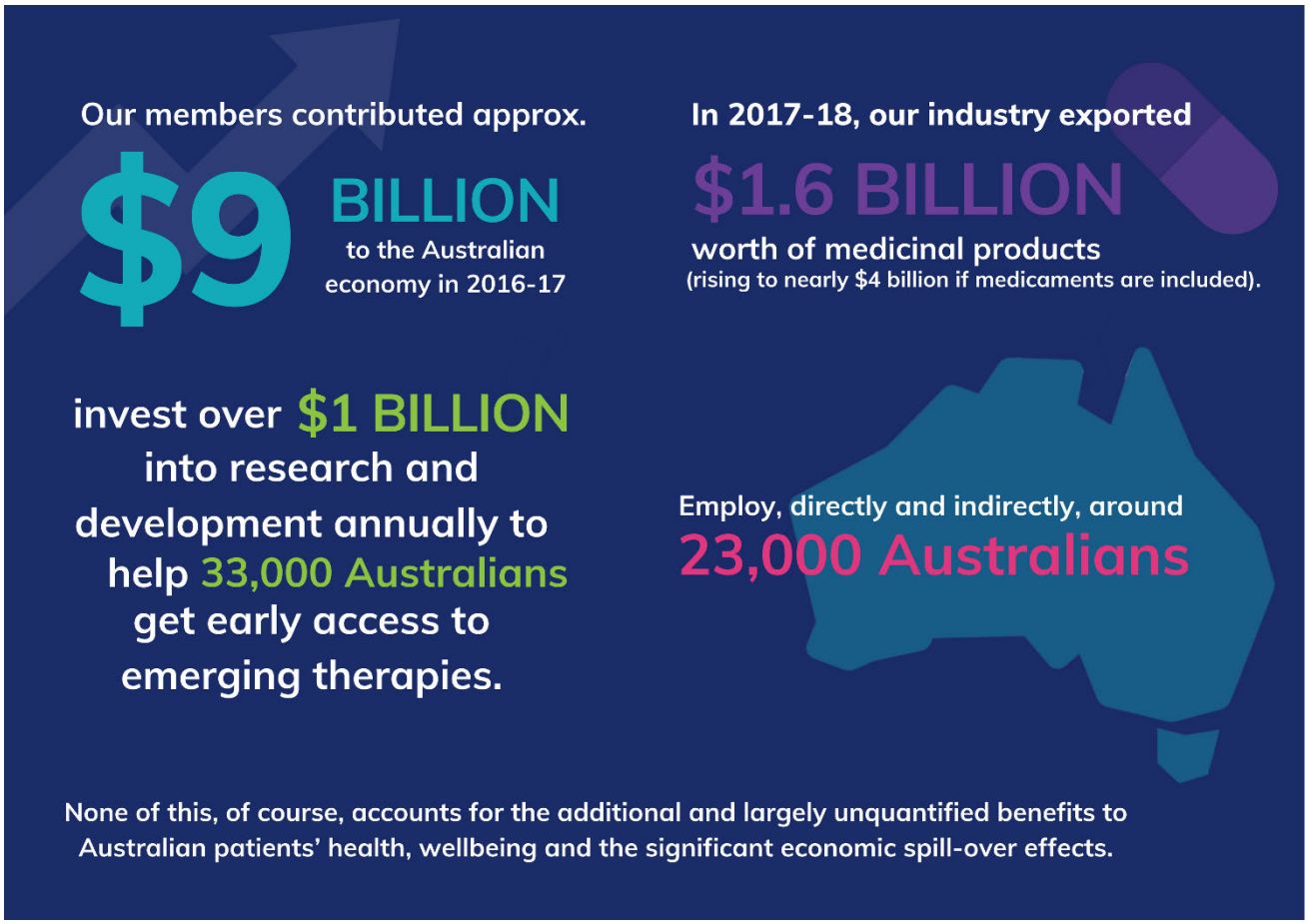
5. That the Federal Government commit to continued investment in medicines through the PBS by:
    a. removing the offset policy for new listings on the PBS, to meet the anticipated needs and expectations of Australian patients, particularly given the important economic benefits from medicines.
    b. continuing to implement the agreed PBS process improvements to shorten time taken from PBAC recommendation to listing
    c. continuing the long-held commitment to list all new medicines recommended by the PBAC
    d. Avoiding unnecessary pressure on the supply chain through policy levers which may lead to lack of access or reduction in patient choice

R&D/Partnerships: (page 22-23)

6. That the Federal Government, <u>at a minimum</u>, retain the current R&D tax incentive for the biopharmaceutical and life sciences sector by carving out this sector from the Treasury Laws Amendment

(Research and Development Tax Incentive) Bill 2019 and aim to strengthen the incentive, to ensure that Australia remains an attractive destination for investment in biopharmaceutical innovation.

7. That the Federal Government expand the JobKeeper payment eligibility criteria to include pre-revenue biotech and medtech companies working in Australia, as these companies are a critical part of the ecosystem and house priceless talent and intellectual property that could be permanently lost to Australia if they are not able to weather the COVID-19 storm.



PART 1: INDUSTRY'S RESPONSE DURING THE PANDEMIC

As the COVID-19 crisis escalated in Australia the innovative research-based medicines industry acted swiftly and effectively to support governments, healthcare professionals, patients, the scientific community and our teams on numerous critical levels. Our intent was (and is) to do whatever is required to support Australia through the extremely challenging events. Our main focus was on the following priorities:

1. Deploy our scientific expertise and capabilities in the fight against COVID-19 – to uncover the urgently needed measures to protect and treat the community.
2. Ensure the supply of essential medicines and vaccines to patients in our hospitals and the community who need them, by working collaboratively with Government, healthcare professionals and consumer organisations to actively manage and pre-empt the healthcare delivery needs as they emerge.
3. Recognise and support Australia's community of healthcare professionals working on the frontline, and the patients they serve.

1. Deploy our scientific expertise and capabilities in the fight against COVID19 – to uncover the urgently needed measures to protect and treat the community.

Research and Development

The fight against COVID-19 will be won if a vaccine can be successfully developed and effective treatments can reduce the impact of those infected.

On a local and global level, the industry is working together, alongside leading research institutions and Governments, to focus research efforts and share expertise – including diagnostic testing capability, potential compounds, new therapies and data on registered medicines and vaccines.

Medicines Australia welcomed the $2.4 billion COVID-19 health package announced by the Prime Minister Scott Morrison in mid -March, aimed at helping Australian researchers to be at the forefront of the drive to develop both treatments and a vaccine. The package included the allocation of $30 million from the Medical Research Future Fund for vaccine, anti-viral and respiratory medicine research.

Medicines Australia's members are actively working with researchers, universities, the CSIRO and each other on a range of initiatives involved in the prevention, diagnosis, treatment and vaccination against coronavirus (COVID-19) both domestically and globally.

The decades-long investments that biopharmaceutical companies have made in new technologies, research and treatments have prepared the industry to act swiftly to respond to the COVID-19 pandemic.

- Industry has deep scientific knowledge gained from decades of experience with similar viruses such as Zika, MERS and SARS.
- Industry has invested billions in technologies that have dramatically shortened the time it takes to decode viruses and develop potential vaccines and it is why we already have existing treatments being tested in clinical trials.
- companies can rapidly scale up production facilities to manufacture vaccines or treatments.

Well over 100 vaccine candidates are in pre-clinical and clinical evaluation[1]. As potential treatments or vaccines are discovered, the industry stands ready to apply its clinical trial expertise to ensure they are safe

[1] https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines

and effective and can be developed as quickly as possible. Global estimates are 80 clinical trials currently underway.

We are also fully committed to the goal of accelerating development, production and equitable global access to safe, quality, effective, and affordable COVID-19 medical products and to ensure that in the fight against COVID-19, no one is left behind. The ACTIV public-private partnership led by the National Institute of Health (NIH) is an example of this commitment (see box).

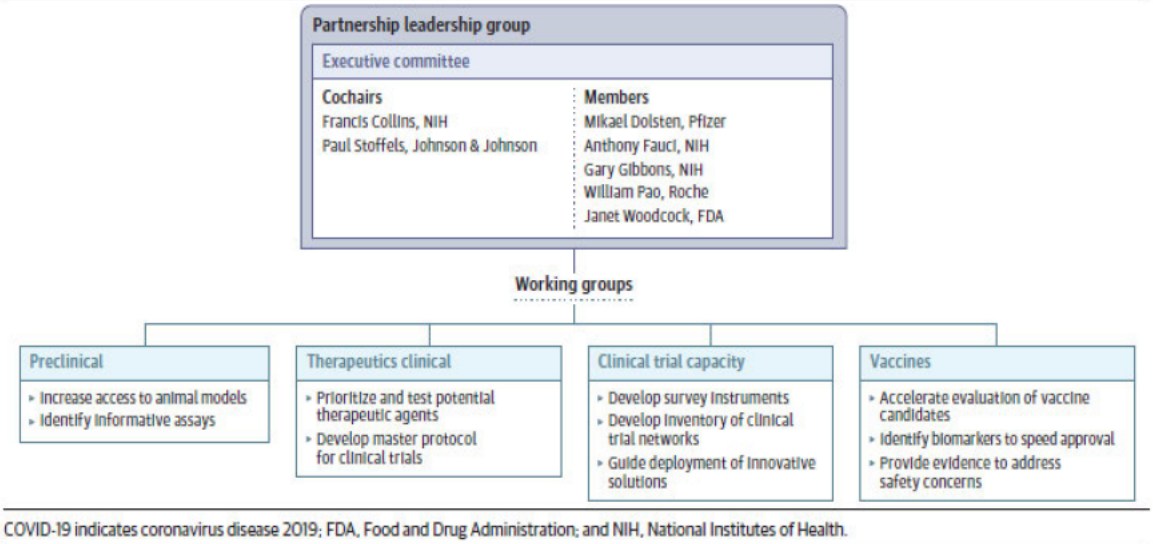
CASE STUDY: UNPRECEDENTED PUBLIC/PRIVATE PARTNERSHIP- ACTIV[2]

On 17 April 2020, the NIH-led *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)* partnership was formally announced. Demonstrating unprecedented commitment, ACTIV's industry partners agreed to support a prioritization of therapeutic and vaccine candidates, no matter who has developed them. Industry partners indicated their willingness to contribute their respective clinical trial capacities, irrespective of the agent to be studied. For their part, the public partners resolved to work at unprecedented speed on research and regulatory issues to drive expedited evaluation and rapid scale-up and manufacturing of candidate therapies with predicted successful outcomes.

The main goals of ACTIV are to establish a collaborative framework for prioritizing vaccine and therapeutic candidates, to streamline clinical trials and tap into existing clinical trial networks, and to coordinate regulatory processes and leverage assets among all partners.

In the short time since the public announcement, ACTIV has continued to expand and attract additional involvement from academia, industry (now 18 biopharmaceutical companies)[3], and government agencies. ACTIV has also taken steps to ensure that the NIH coordinated initiative is closely interconnected and complementary with other COVID-19 efforts, including those led by the FDA and BARDA's Medical Countermeasures Task Force, as well as international initiatives led by the Bill & Melinda Gates Foundation, the Wellcome Trust, the European Commission, the UK government, and the World Health Organization.

Figure. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Partnership



COVID-19 indicates coronavirus disease 2019; FDA, Food and Drug Administration; and NIH, National Institutes of Health.

[2] "Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) An Unprecedented Partnership for Unprecedented Times", JAMA published online May18 2020

[3] It is noteworthy that many of the organisations involved in the ACTIV partnership have a presence in Australia and could bring COVID-19 clinical trials to Australia, as well as any vaccine. These include: AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Eli Lilly, MSD, Novartis, Pfizer, Roche, Sanofi and Takeda.

Maintaining clinical trials

Medicines Australia has been working in lockstep with industry, clinical experts and government to ensure that clinical trials continue and are supported throughout Australia, where safe and viable to do so. The industry-led Research and Development Taskforce (RDTF) has played a leadership role in aligning public and private stakeholders views and expectations around ongoing clinical trials, releasing a position statement on 23 March 2020, "Supporting Clinical Trials During the COVID-19 pandemic." [4] Important strategies were applied to help trials remain on foot such as activating telehealth solutions, remote monitoring, medicines delivery and/or home administration. We also acknowledge the complementary advisory statement released by the Clinical Trial Project Reference Group, which provided additional clarity and support for the conduct of clinical trials during COVID-19.

Medicines Australia has surveyed its members regularly throughout the pandemic to understand and identify any barriers and challenges. Insights from our members is shown below

Medicines Australia Member COVID-19 Clinical Trials Insights

Insights from Medicines Australia members on clinical trials during the COVID-19 pandemic.

Medicines Australia members sought to continue and start trials where safe and viable to do so. While members adapted their protocols where they could, the lack of a nationally harmonised system, such as for remote monitoring or utilising digital solutions, hampered efforts.

Initiating clinical trials

During the COVID-19 pandemic many pharmaceutical companies faced challenges in starting and continuing clinical trials. The challenge was to ensure that patients could still participate in clinical trials and receive adequate care, while ensuring that they were not are risk from exposure to COVID-19.

In early April pharmaceutical companies had begun to report how they were changing their plans for initiating new clinical trials. Early changes were reported as hospital ethics committees began to stop approving new trails, forcing companies to delay recruitment for new trials, and some stopped some plans for new trials altogether. However, at this stage there did not seem to be a blanket approach.

As mid-April approached it became clearer that companies would need to consider delays to the planning of new trials. Although some were being considered on a case-by-case basis, many companies reported that trails that were planned for the first quarter of 2020 were now delayed or postponed until later in the year.

During the middle of May, this status had been updated by several companies. Many now reported that they were looking to go ahead with trials alongside research partners, previously approved before the pandemic. Companies were actively looking to identify where these new trials could begin, but only if it were safe to do so.

Existing clinical trials

In early April, companies provided a mix of responses about the status of existing clinical trials. While some companies reported no change to non-COVID related trials, others reported that there would be no more recruitment for new patients for existing trials, and some noted that they had already halted and stopped trials all together.

[4] https://medicinesaustralia.com.au/rdtf-joint-position-statement-supporting-clinical-trials-during-the-covid-19-pandemic-23mar2020/

By mid-April, the consensus seemed to become slightly clearer, and most companies reported that there had been a change to the way existing trails were being conducted. Companies were putting in place a range of practices to ensure patient safety while continuing treatment, and this included keeping some sites open, but ensuring that social distancing measures were in place at the sites.

Some companies utilised external facilities, at sites separate from the primary site, to conduct tests (i.e. pathology tests).This included some sites for oncology patients, as these sites had been relocated away from hospitals and away from COVID testing clinics. Additionally, companies reported directly shipping products to patients to ensure continuity of supply of the medicines.

Many companies reported that the recruitment of new patients in existing trials had been suspended. Others reported developing alternative solutions to providing patients with ongoing assistance even if they were no longer able to complete a site visit. This included using virtual options where recommended by site managers including telehealth visits, virtual monitoring, and where possible, setting up home nursing for those who were unable to make site visits.

Moving into May companies were reporting different strategies on the next steps for existing clinical trials, including postponing commencement, utilizing remote monitoring options and working with State Health Departments on where and when they could restart their trials.

The lack of nationally harmonized guidance and standards were a challenging aspect of remote trials. Changing trials sites also created challenges for pharmaceutical companies and their staff working in the clinical trials space. Some reported that interstate travel restrictions had a significant impact on successfully completing their work, as these positions were generally national roles that required interstate travel.

Regulatory initiatives

Any vaccines or treatments for COVID-19 will need to go through robust regulatory processes to ensure their quality, safety and efficacy.

On the regulatory front, Medicines Australia has seen a strengthened resolve between industry and regulators to work together. In Australia, the Therapeutics Goods Administration (TGA) is engaged closely with all parts of the industry. Medicines Australia is working collaboratively with the TGA and other industry stakeholders in addressing localised and national medicines shortages issues before they become critical, and on industry challenges relating to registration, licensing and good manufacturing practices.

Internationally, Medicines Australia is working with its peak pharmaceutical body counterparts through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Pharmaceutical Research and Manufacturers of America (PhRMA) and others.

The IFPMA is reaching out to the International Coalition of Medicines Regulatory Authorities ((ICMRA) co-chaired by the TGA) to address regulatory challenges posed by COVID-19. This includes closer cooperation between industry and regulators to ensure potential COVID-19 treatments and vaccines are assessed in a timely manner and reach patients quickly.

The industry strongly supports ICMRA's recent statement on COVID-19 and willingness to foster international alignment on regulatory best practices and policies, including plans to "align on regulatory requirements and collaborate on accelerated procedures from the development to the approval, including rolling reviews and approval of trials, drugs, biologics and vaccines".

Rapid scientific assessment pathways for COVID-19 medical products are being put in place, and it will be important that their implementation leverages existing collaboration between national regulatory authorities, while including appropriate dialogue and exchange with manufacturers.

The global industry has proposed to establish a forum for discussion between representatives from ICMRA and industry associations of drug and vaccine innovators. Discussion would focus on the principles for early collaboration and shared scientific assessments across national regulatory authorities, noting that there are good collaborations already in place through other platforms.

Innovative approaches to generate data will be needed to accelerate development timelines for new drugs and vaccines or re-purposed therapies for COVID-19, while maintaining rigorous scientific standards. The local industry is keen to work with the TGA to share and implement any learnings from accelerated development programs and other initiatives. For example: appropriately exploiting prior knowledge, platform technologies and quality risk management to support information in the CTD Quality module; initial manufacture and supply from development facilities, etc.

2. Since the start of the pandemic, maintaining supply of medicines and vaccines to Australians has been our critical priority.

The ongoing supply of essential innovative medicines and vaccines to Australians who rely on them remains the priority commitment for industry – including provisions for the COVID-19 emergency response for hospitals and vital medicine needs within the community.

Medicines Australia and the medicines industry has been working collaboratively with the Government and the TGA as an integral member of the Medicines Shortages working group, to ensure that these supply chains remain uninterrupted and there is early notification and mitigation of medicines shortages.

As an industry our companies are working around the clock to monitor and assess our supplies, locally and globally, to ensure they can get to where they are needed. This includes increasing production, identifying alternative sources of supply and acknowledging the diversity of the supply chain that protects the originator companies from reliance on single sources of supplies.

The response to the COVID-19 pandemic led Medicines Australia to build five *Critical Medicine Supply Priorities* to support the ongoing and responsible management of Australia's vital medicines supplies and reinforce and extend medicine supply strategies for the immediate short-term (over the coming months) as elective surgery recommences fully and more Australians return to their more regular doctor interactions:

1. Discourage Stockpiling or Panic Buying. Stockpiling or panic buying of medicines must not take place. This causes unnecessary surges and spikes in demand for medicine supplies – which can result in pharmacy stock-outs if large orders are fulfilled. In this regard, we have endorsed the Government messages to reassure patients and the community that their medicines are available and stockpiling is unnecessary.[5]

[5] **19 March 2020 – Media Release: No need to stockpile medicines says MA Chief -**Medicines Australia CEO Elizabeth de Somer has echoed calls by the Prime Minister Scott Morrison, for Australians to stop stockpiling medicine during the ongoing COVID pandemic; **19 March 2020 - MA welcome the Government's actions to ensure continued access to medicines -**Medicines Australia CEO Elizabeth de Somer has welcomed today's announcement by the deputy Chief Medical Officer Professor Paul Kelly introducing limits on dispensing certain prescription medicines and other pharmaceutical products such as Ventolin and children's Panadol to address unnecessary panic purchasing at community pharmacies.

2. Encourage adherence to Monthly Quantities Prescribed and Dispensed during COVID-19. It is important for medicines to be prescribed in quantities that cover a patient's immediate needs, as we respond to the COVID-19 crisis.
3. Prioritise the Movement and Distribution of Medicines. The movement of medicines into the country and distribution around our nation must be prioritised. We thank the Government for their support in helping to bring medicines into the country via airfreight, and wholesalers who are moving medicines to pharmacies and hospitals. We thank pharmacists for managing dispensing pressure and helping with home delivery needs. We also thank Australia Post for giving further home delivery support. These initiatives have been welcomed by patients and consumers and would advocate for them to continue beyond the crisis, as it is convenient for patients, particularly the elderly, vulnerable and immunocompromised.
4. Provide Clear Public Information on the Medicines Shortage Lists and Protocols to Manage Shortages. We have asked government to introduce consumer friendly information for patients to the lists of medicines it currently publishes. In addition, greater detail on what measures are implemented should a national shortage occur – so that healthcare professionals and patients clearly understand the comprehensive protocols in place and what they need to do.
5. Encourage Patient Interactions with their Doctor and Pharmacist. We know patients are feeling anxious and actively encourage them to interact with their doctor and pharmacist to discuss their concerns with any of their medicines. Telehealth has provided a safe way for patients to keep connected with their healthcare professional which reduces their anxiety and helps them to maintain their regular health routines. Patients can also reach out directly to the manufacturer if they have concerns about their medications and supported patients to access medicine supply.

In support of these priorities, Medicines Australia implemented several key initiatives:

A. Active tracking, monitoring and managing the supply chain by surveying our members daily over the past few months to identify any supply issues (see separate box).

Medicines Australia members identified several issues at different stages of the pandemic including import and export challenges due to freight restrictions and the closing of international borders, and provided relevant information to Government.[6]

At the same time there was a significant spike in the demand for medicines as many patients and consumers, and State Governments looked to stockpile and hoard medicines. Early concerns about the magnitude of virus-affected patients persisted, driving demand, despite evidence showing these expectations were unlikely to be realised.

Medicines Australia Member COVID-19 Supply Chain Challenges

Insights from Medicines Australia members on global supply chains during the COVID-19 pandemic.

[6] For example, **Thursday 9 April 2020 - Airfreight a critical priority for Australia's medicines supplies**
Medicines Australia is urging the Federal Government to ensure international air freight and commercial flights continue to operate so medicines and medicine supplies can continue to arrive into Australia – both for COVID-19 emergency needs and existing health conditions within the community.

Supply chain challenges

Since the start of the pandemic, monitoring the supply of medicines has been a critical priority of Medicines Australia. Medicines Australia undertook the process of surveying members daily at the height of the pandemic to capture all supply-related challenges and complications.

Freight

During the COVID-19 pandemic many pharmaceutical companies experienced freight challenges. While there were notable delays in freight of products by sea, the vast majority of responses by companies who were experiencing challenges in the supply of medicines were in relation to air freight.

The COVID-19 pandemic saw widespread lockdown of international borders, resulting in the grounding of a large proportion of international and domestic air travel. This significantly impacted the medicines supply chain, which is a highly globalized web of manufacturing, production, R&D and distribution.

The reduction in flight numbers led to many medicine manufacturers losing reliable import routes to Australia, with many reporting challenging timelines for supply due to flight delays and cancellations. The logistics onus fell upon these companies who were required to work with multiple airlines and multiple jurisdictions to find alternatives to ensure supply would reach Australia.

An ongoing challenge with sourcing alternate routes was the lack of available cargo space on many flights. These delays alongside the increased competition for freight space resulted in increases to freight costs.

These costs should not be underestimated as some members highlighted that the experienced increase in costs were so large that some goods (particularly PPE) were worth less than the freight cost to move them. Some companies noted that at one stage, the cost of freight had increased to six times the normal rate.

The delays and restricted movement challenge for companies was notable as it was probably for the first time in a modernized global world where supply issues were almost all over the globe. Every major medicine supply location in the world was adversely affected by COVID-19 and this resulted in supply challenges across the globe.

This included many European nations such as Italy, Germany, France, Switzerland and the Netherlands which are the home to a number of multi-national pharmaceutical companies. It also included major distribution points in Dubai and Singapore and included the large scale manufacturing zones of India and China. Delays were also experienced in Korea, the United States and in New Zealand.

Exports

While the primary focus during March and April was on the global supply chains where medicines were imported to Australia, there was also challenges for pharmaceutical manufacturers who export products from Australia.

As global freight options diminished, it was just as hard for some companies to move products out of Australia, to overseas destinations. This included moving stock to both Europe and to Asia, with limited cargo space on the air freight options that were still running.

Not only was international export an issue, but some manufacturers had added challenges of moving stock across state borders which had been closed due to COVID restrictions. This created challenges where some manufacturers needed to transport (often cold chain) stock across state lines so that they could export stock internationally.

Demand for Medicines

During March and early April there was a significant demand spike for medicines, driven by consumer stockpiling behaviour. Companies reported seeing demand spikes for stock that were at levels well above average for the time of year, and well above the levels that were forecast.

This demand spike started with companies reporting increases in the range of 10 % to 30%, but soon increased to the range of 100% to 200%, and for some medicines as high as 300% in early April. This increased demand saw a reduction in the levels of some safety stock, and it saw the need for the Federal Government to step in and enforce restrictions.

At the same time companies came under pressure from some State Governments, advising them that they would be looking to procure and stockpile six months base stockholding of pharmaceutical products across all essential medicines. This was a move that put unnecessary pressure on manufacturers to replenish the supply chain at a time when they were calling for calm.

It was not until late April that medicines manufacturers reported that the demand had begun to normalize. Even as late as mid-May some manufacturers still reported that demand levels for some products were higher than forecasted.

Government support

During this period of heightened demand from consumers and State Governments, medicines manufacturers were able to manage their supply chains with continued close collaboration with the Federal Government. Many manufacturers were able to contact the Government team responsible for planning specialized flights that could be backloaded with medical supplies to Australia.

B. Interim authorisation from the ACCC:

Medicines Australia initiated an application to the Australian Competition and Consumer Commission (supported and joined by the Generic and Biosimilar Medicines Association (GBMA)) to seek authorisation to work together and with the Government on managing the supply of critical medicines. Medicines Australia and GBMA were granted interim authorisation from the ACCC on 3 April 2020 to allow medicine suppliers to collaborate more closely on managing supply and stocks for Australia. The authorisation applies to members of MA and the GBMA, and other relevant medicine suppliers who are notified to the ACCC.

This important step is in the national interest and places pharmaceutical companies in the best possible position to manage the unprecedented COVID-19 situation and supply of prescription medicines.

Medicines Australia and the GBMA are working extremely closely with their members to monitor, pre-empt and address any medicine supply issues resulting from COVID-19. This includes continuous monitoring and assessment of stock and supply of specific medicines locally and globally, together with the management of priority and urgent needs relating to transportation and freight.

C. Close partnership with Federal (and State) Governments

The Medicines Shortages Working Group, comprised of key representatives across the medicines supply chain, convened by the Federal Department of Health through the TGA in 2017 to develop an enhanced approach to medicines shortages notification, was reconvened in response to COVID-19.

Additionally, a sub-group that brings together MA, GBMA, NPSA and the TGA was convened on specific issues. This has facilitated close collaboration with the government on the response to COVID-19 particularly in relation to medicines.

The Medicines Shortages Working Group has met weekly since early March to consider the impact of COVID-19 on medicines shortages at a national level as well as local stock outs at the pharmacy level; review surveys conducted by retail and hospital pharmacy; and identify emerging issues with medicines supplies. The group has worked closely with the hospital pharmacists with input from the State and Territories to understand the demand and supply arrangements in relation to ICU medicines. The targeted subgroup has reviewed the impact of supply restrictions on the availability of medicines through the supply chain from manufacturers to wholesalers and stockpiling, hoarding behaviour.

Medicines Australia has also contributed in parallel to the weekly multi-stakeholder supply chain roundtable led by the Minister for Industry, the Hon Karen Andrews, the Minister's office and the Department of Industry, Science, Energy and Resources (DISER). These industry roundtables identified the similarities of issues across sectors and highlighted a range of opportunities for the Department to assist and respond, for example in the development of the International Freight Assistance Mechanism (IFAM).

Additionally, Medicines Australia has provided continuous status updates to the TGA on all medicine supplies and importantly those on the high priority list, over and above the standard monitoring procedures. We are also interacting regularly and are providing frequent updates to several other government departments, including DISER, Department of Foreign Affairs and Trade (DFAT) and Department of Home Affairs to ensure a reliable two-way flow of relevant supply chain information. Medicines Australia also facilitated a range of 1:1 virtual meetings between Minister Andrews and medicines manufacturers and suppliers of critical products for the COVID-19 response, including vaccines, diagnostic tests, ICU medicines and other critical supplies.

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 to ensure 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 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.

During Hurricane Maria in 2017, approximately 50 pharmaceutical manufacturing facilities in Puerto Rico had their capacity impacted by the disaster. Because of their robust supply chains, the industry was quickly able to source from facilities in other areas and prevent long-term drug shortages.

3. Recognise and actively support Australia's healthcare professional community working on the frontline, together with the patients they serve

As a responsible industry we are continuing to support Australian healthcare professionals working on the frontline both in hospitals managing the COVID-19 response and also in the community managing the Nation's general health. The health of patients, the community and healthcare professionals who take care of our health are the industry's utmost priority and will continue to be as this crisis continues.

During this unprecedented time, we are ensuring patient groups and healthcare organisations are kept fully updated with information to share with their communities. Patient safety and continuity of care have never been more important.

We are leading and supporting new and innovative ways to interact with patients and the healthcare community to ensure new forms of healthcare delivery – including treatment within the home, remote telehealth capabilities and virtual training are fully maximised, meeting the Nation's ongoing health needs .

Continuity of Care Collaboration

Right now, more than ever, it is essential Australians maintain their health to support a purposeful recovery. Therefore, Medicines Australia is pleased to be one of the founding members of the **Continuity of Care Collaboration.**

The Continuity of Care Collaboration (CCC) is an Australian-first national communication collaboration of over 30 Peak Bodies, Industry and Healthcare Organisations coming together to stress the importance for people to continue monitoring their health and maintaining their regular medical care[7]. Some members include Royal Australian College of General Practitioners (RACGP), Australian Medical Association (AMA), Pharmacy Guild and Consumer Health Forum.

The group has formed amid mounting concerns that Australians are not maintaining their regular doctor visits for existing chronic conditions and/or putting off seeing their doctor to get a test, investigation, or immunisation due to fears of contracting COVID-19 or burdening the health system. Understandably, during our lockdown the rates of visits to general practice, allied health professionals and emergency departments have dropped. There has also been a large drop of about 40% in the number of pathology tests being done. (Source: Royal **College of Pathologists**)

Continuity of care consists of 7 key areas and these include Prevention; Chronic Disease Management; Vaccination, Cancer Screening, Adherence to Medicines Acute Care Management; and Pathology Testing.

[7] This is an issue which Medicines Australia has prosecuted throughout the pandemic. For example, **Tuesday 21 April 2020 – Elective surgery restarts but with growing concern Australia's post COVID-19 health hangover ma have deep impact -**Medicines Australia welcomes today's announcement by Prime Minister the Hon Scott Morrison that elective surgery will "gradually restart" from next week following nearly a month of suspension – but urges increased concurrent attention on Australia's chronic health care needs to help reduce a significant post COVID-19 health hangover.

Across the board, from GP visits, to pathology, to screening, to acute care presentations, we have seen a significant drop off in Australians taking care of their health. And while this is understandable due to the COVID-19 pandemic, it could lead to significant long-term health consequences and costs for the patient and the community.

By not seeking treatment now, it could also mean that there will be a heavy influx of people needing treatment down the track, which will place undue burden on the health system precisely when it needs to be managed very carefully. We also run the risk of people delaying getting diagnoses of serious disease and cancers, leading to worsening of long-term health outcomes.

The CCC will measure its success when consumers feel safe, equipped and confident to access usual care during the pandemic and there is an increase in testing, clinic visits, immunisations – back to at least baseline seen prior to COVID-19.

The CCC have also conducted a consumer survey to gauge barriers to access and consumer sentiment, with a focus on ensuring continuity of care. Survey results will be shared in due course and will further highlight areas of concern. The results will help to shape strategies and communication messages for consumers and patients.

The CCC has developed an open letter to mainstream media calling for all Australians to maintain their health and continue with their regular health routines if they have a chronic disease.

Educating Consumer and Patient Groups on the Supply Chain

Medicines Australia hosted a consumer round table of some 16 consumer and patient organisations, with participation from the TGA and a facilitated discussion by Consumer Health Forum on the complexities of the medicines and vaccines supply chains and how the government and industry have worked together to ensure the supply of medicines during COVID-19.

The roundtable was also an important opportunity to gain consumer feedback on current issues and how improvements can be made moving forward to ensure continued access to medicines for all Australian patients. Medicines Australia will provide the Department of Health with a report outlining the findings of the roundtable and proposed considerations.

Medicines Australia will continue to proactively engage with the government and consumer groups, to ensure clear understanding of the role that industry and government are playing in the continuous supply of critical and innovative medicines.

Industry Supporting Consumer and Patient Groups

Medicines Australia's Consumer Working Advocacy Group (CAWG) are working with PwC to develop tailored educational seminars to support consumer and patient organisations in building resilience, sustainability, and capacity to manage the 'road out' of the COVID-19 pandemic.

Medicine Australia liaises with over 130 consumer and patient organisations within the network, ranging in size, scale, complexity, and sophistication, and with different operating and financial characteristics.
The CAWG and PwC will tailor a series of programs that are accessible and relevant to all consumer and patient organisations, with the potential to lead to more focused assistance for more financially vulnerable groups in the network.

Medicines Australia also welcomed the Australian Government's efforts to improve the tracing of COVID-19 with it COVIDSafe app[8], and encouraged its network of patient organisations, and the over 23,000 employees of Medicines Australia member companies to sign up.[9]

[8] **Monday 27 April 2020 Medicines Australia Welcomes COVID-19 Tracking App -**Medicines Australia has today welcomed the COVID-19 tracking app COVIDSafe, which will help keep the community safe from further spread of coronavirus through early notification of possible exposure.
"This app is crucial during these challenging times – for those fighting COVID-19 in our hospitals and in order to protect the most vulnerable within our communities," said Elizabeth de Somer, CEO Medicines Australia.
[9] **Wednesday 29 April 2020 - Medicines Australia encourages employees of the medicines industry to download the COVIDSafe App.**

PART 2: THE KEY OPPORTUNITIES THAT HAVE OPENED FOR A HEALTH-LED RECOVERY OF THE AUSTRALIAN ECONOMY

With COVID-19, the nation's overall health and economic wealth have never been more clearly linked. We also recognise COVID-19 has reinforced the importance and value of science and innovation – our core competencies. It has also generated new efficiencies and positive outcomes resulting from the rapid implementation of advancements in health delivery to healthcare professionals and patients (telehealth mechanisms, at home care, home delivery).

Prioritising and investing in innovative and advanced health strategies, together with the scientific community, will help to build a purposeful economic recovery and future proof Australia. These important health-based recovery strategies include:

- Positioning Australia as a global clinical research centre of excellence opening up for business once again to conduct trials/research
- Committing to the timely introduction and broad access to innovative medicines and advancements in healthcare delivery
- Supporting a robust healthcare ecosystem that forms partnerships and collaborations to innovate, develop and manufacture high-quality/high-tech biopharmaceuticals and contributes to the delivery of high value jobs, highly skilled STEM-enabled workforce
- Adopting critical learnings and new efficiencies from the COVID-19 health response

It is important now to prioritise health not only to manage COVID-19 effectively but also to forge a future economic path for Australia. A strong trajectory in the advancement and evolution of healthcare delivery and maximisation of innovative medicines will be critical for success.

Igniting a renewed 'health ambition' in Australia to step-up to global benchmarks in science and innovation, will place us in the strongest possible position to build a prosperous future.

1. Positioning Australia as a global clinical research centre of excellence re-opening for business to conduct trials/research

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.

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 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.[10]

In bringing more of those trials here, we have the chance to grow Australia's clinical trials sector, strengthen international collaboration, raise levels of expertise and treat more patients.

All this strengthens R&D capabilities, but also strengthens the health care system in metropolitan and rural areas. The fast implementation of tele-health during COVID-19 and the opportunities presented by remotely running clinical trials, including in rural areas through a tele-trials model, can re-shape the sector.

Embedding clinical trials as part of the health infrastructure's standard of care will improve our health-care system, strengthen R&D and improve patients' health outcomes.

If Federal and State Governments work closely together to harmonise processes for faster and more efficient start-up of trials – ethics, governance and recruitment – then Medicines Australia members and other research based organisations will be better equipped to attract clinical trials and FDI into Australia. Each State should be commended for their interest and efforts to attract clinical trials at an individual State level. The key to take 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.

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.

These steps include, among other things, national messaging that Australia is open for business, a front door that streamlines ethics and governance processes (clinical trial harmonisation), and consistent standards on remote monitoring and utilising digital technology.

Recommendations:

That Federal and State Governments work together with industry, through Medicines Australia and the Research and Development Taskforce (RDTF), to:

a. Promote domestically and internationally that Australia is open for business to conduct clinical trials
b. Embed clinical trials as part of the standard treatment of care in the national health infrastructure, including regionally through clinical tele-trials
c. 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
d. Strengthen the capacity to conduct clinical tele-trials in rural, remote and regional areas
e. Develop nationally agreed clinical trials standards and guidance on
    i. tele-health
    ii. tele-trials

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

iii. remote monitoring (including delivery and management of Investigational Medicinal Product)
iv. the utilisation of digital technology, such as access to electronic Medical Records (eMR), e-signatures and e-consent

f. 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.

2. Committing to the timely introduction and broad access to innovative medicines and advancements in healthcare delivery

COVID-19 has highlighted the importance of maintaining timely, affordable, and reliable access to medicines and vaccines and that medicines are an investment worth making.

We acknowledge the Government has worked hard to ensure new medicines continue to receive listing on the PBS during this challenging time. Maintaining the arrival of innovative medicines and advanced health technologies are important elements during this delicate period – and also for the future. We believe a health led recovery must form a critical part of the Australian government future proofing the economy.

Medicines are an integral component of healthcare and help Australians live longer and healthier lives; remain productive and employed, out of hospitals and positively contributing 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.

There is a direct connection between the listing of innovative medicines and benefits to the health and wellbeing of Australians. However, broader economic benefits from the listing of these medicines also offset costs across the wider government budget. The cost of early retirements due to ill health on GDP was estimated to be $45.3 billion in 2017 and expected to increase to $53.4 billion in 2025. Effective health programs, such as listing of new medicines, can reduce these costs by up to 20%.[11]

New medicines help reduce the days of hospital care for Australians, helping to reduce hospital expenditure. It is estimated that hospital expenditure in 2015 was reduced by $3.47 billion because of planned investment in medicines in the decade prior.[12] These examples demonstrate the true value of the PBS, and why investment in medicines has a significant positive influence on the economy.

The impact of health improvements on gross domestic product has been well documented in a report from the Australian Government's Office of the Chief Scientist[13] which had a special focus on the biological sciences.

Given the importance of innovative medicines, it is concerning PBS expenditure (less rebates) as a proportion of the GDP has fallen from 0.74% in 2009-10 to 0.57% in 2018-19 and is projected to continue to

[11] 2018, The McKell Institute, '*Our Health Our Wealth, The Impact of Ill Health on Retirement Savings in Australia*', Accessed 5 December 2019: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/09/Our-Health-Our-Wealth-full-report.pdf sponsored by Medicines Australia, 2018.
[12] 2019, Lichtenberg F. *The Impact of Pharmaceutical Innovation on Premature Mortality & Hospitalization in Australia 1998-2018.*
[13] Australian Government Office of the Chief Scientist. The importance of advanced biological sciences to the Australian economy. January 2016. The report noted that if a 10% health improvement were applied to the entire working age population (say, 18 to 69), the expected change in GDP would be around 0.216%, or $2 801 million. `The estimated impact of advanced biology on health outcomes was 18% to 34%; this means that the expected change in GDP may be between $5 042 million and $9 523 million.

fall at the current rate of investment.[14] Using the projections of GDP growth presented in the 2019-20 Budget,[15] PBS expenditure as a proportion of GDP is projected to fall significantly at an annual rate of 3.39% over the forward estimates. This would see PBS expenditure at only 0.49% of GDP by 2021-22.

Australia's PBS has delivered universal access to medicines for Australians for 70 years and continues to do so in a fiscally self-sustaining manner. It has helped to improve the health and well-being of many Australians. In return the Government has been repaid with increased productivity and broader economic prosperity, contributing to Australia's strong economy.

However, medicines investment over the forward estimates show that investment levels risk falling behind a growing and ageing population, and current trends in F1 and F2 medicines listings. In this challenging time stalling the nation's capacity to continue to introduce innovative medicines and advances is an area for Government to address.

The COVID-19 pandemic has also exposed some of the flaws in the system which NZ has adopted. There are lessons to be learned from PHARMAC – a flawed and fragile system with an overreliance on sole suppliers and single source nations.
It is worth noting that the proposed review of the National Medicines Policy provides an opportunity to consider all aspects of the timeliness, affordability, and quality of new medicines and the industry which delivers them.

Recommendations

That the Federal Government commit to continued investment in medicines through the PBS by:

a. removing the offset policy for new listings on the PBS, to meet the anticipated needs and expectations of Australian patients, particularly given the important economic benefits from medicines.
b. continuing to implement the agreed PBS process improvements to shorten time taken from PBAC recommendation to listing
c. continuing the long-held commitment to list all new medicines recommended by the PBAC
d. Avoiding unnecessary pressure on the supply chain through policy levers which may lead to lack of access or reduction in patient choice.

3.Supporting a robust healthcare ecosystem that forms partnerships and collaborations to innovate, develop and manufacture high-quality/high-tech biopharmaceuticals, and contributes to the delivery of high value jobs and a STEM-enabled workforce

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.

R&D is key. Partnerships are essential.

Encouraging an ecosystem of partnerships that innovate, develop, and manufacture high-quality/high-tech biopharmaceuticals and vaccines (see case study on Gardasil) should form a central component to a health led economic recovery. This may open the door to the possible niche bio-pharmaceutical manufacturing and

[14] **Source**: Final Budget Outcomes various years, Department of Health Annual Report various years, 2019-20 Federal Budget forward estimates, ABS catalogue 5206.0 GDP figures, ABS catalogue 3222.0 population projections, Department of Health Trends and Drivers of PBS expenditure 2013, National Health (listed drugs on F1 or F2) Determination 2010, various months.
[15] In the 2019-20 Mid-Year Economic and Fiscal Outlook GDP growth in nominal terms is projected to be 5.3% in 2018-19, 3.25% in 2019-20, 2.25% in 2020-21, and 4.75% in 2021-22 and 2022-23.

other health related innovations, including medical devices and software, that support high value/highly skilled jobs.

CASE STUDY[16]

Gardasil

The problem: cervical cancer

Cervical cancer causes 250 000 deaths worldwide each year (Frazer 2014) and was forecast to cause 250 deaths in Australia in 2015 (Cancer Australia 2015). Before the discovery and development of the vaccine Gardasil, no vaccine was available. If a woman is diagnosed with cervical cancer, treatment options include surgery (to remove cancers from the cervix), radiotherapy and chemotherapy. Those treatments have significant negative side effects. If the cancer has spread out of the pelvis, it is not usually considered 'curable'. Partial solution: discovery of Gardasil vaccine which acts as a vaccine against cervical cancer and anal cancer by preventing infection with the virus that causes then, the human papillomavirus (HPV). It introduces non-infectious virus-like particles that mimic the HPV virus into the body. This activates the body's natural immune response, which protects against future infection by the real HPV virus.

The development of the vaccine started in 1991 with the expression of the human papillomavirus L1 and L2 proteins together. The vaccine was further developed in the early 1990s by research groups from around the world who expressed the proteins in different forms, including groups from the University of Queensland, Georgetown University, the National Cancer Institute and the University of Rochester (McNeil 2006). Once the technologies for the vaccines were developed, two different vaccine companies then developed and tested products in clinical trials for commercial development (Frazer 2014).

The development of Gardasil is a clear example of how biological research conducted collaboratively by different people and institutions around the world has significantly increased knowledge and understanding and resulted in tangible improvements in health outcomes. Australian researchers played major roles in the research efforts.

Australia's competitive advantages are held in its people, its infrastructure, and its reputation in producing safe and high-quality biopharmaceutical products. Australia has a strong track record of extraordinary talent in science and technology, quality niche and advanced manufacturing, best practice regulation and a first-class health and medical system.

Playing to these strengths provides opportunities 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.

With the right policies, we have the potential to upgrade manufacturing and strengthen supply chains to meet Australia's future pandemic needs and respond to other crises. These 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 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

[16] Cited in Australian Government Office of the Chief Scientist. The importance of advanced biological sciences to the Australian economy. January 2016

Initiative in 2017. Policy options to enable capabilities can then be targeted to achieve the required investment.

The bio-pharmaceutical industry, represented by Medicines Australia, is an active participant in the efforts to better develop Australia's medicines capabilities. The success of the ecosystem will be enhanced by strong public-private partnerships domestically and linked globally.

The life sciences sector encompasses more than 1,800 organisations and 240,000 employees.

In 2017-18, MA members 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.

Start-ups and SMEs account for 86 per cent of the life sciences industry and employ more than 65,000 Australians in high-value jobs. Many of these are still purely in the R&D discovery and pre-revenue generating phase of their business development. The sector has been adding more than $4 billion gross value per annum to Australia's economy, and, to date, is a world leader with a strong track record in developing new therapies to combat devastating disease.

Australia's pre-revenue biotech and medtech companies house priceless talent and intellectual property that could be permanently lost to Australia if they are not able to access the Government's JobKeeper assistance to weather the COVID-19 storm. The Australian Taxation Office recently denied the industry's application to expand the JobKeeper payment eligibility criteria to include pre-revenue biotech and medtech companies working in Australia.

JobKeeper's intention is to retain staff and to support businesses to recommence quickly without needing to rehire when the downturn is over. Omitting pre-revenue life science companies has the potential to knock over the entire industry – companies will be 'moth-balled', innovative research (predominantly clinical trials) parked, and staff let go. These companies represent an important part of the ecosystem.

Better commercialisation platforms to keep discoveries and their intellectual property in Australia are also required. A culture that values public/private partnerships needs to be fostered, including through government R&D grants, tax incentives and the promotion of venture capital opportunities to fund and commercialise discoveries.

In this regard, Medicines Australia believes the current R&D tax incentive plays a major role in maintaining Australia's competitiveness as a preferred location for R&D activities. The Bill currently in the Federal Parliament will, if passed, significantly weaken the life sciences sector in Australia and Australia's attractiveness as an innovation location and investment destination.

Recommendations

That the Federal Government work with the private sector, through Medicines Australia, to review the current capacity of the sector and identify opportunities to enhance industry capabilities. Expanding Australia's contribution to the global innovative medicines industry, from discovery to patient access, would future proof the economy. Policy options to enable this capability building can then be targeted to achieve the required investment.

That the Federal Government, at a minimum, retain the current R&D tax incentive for the biopharmaceutical and life sciences sector by carving out this sector from the Treasury Laws Amendment

(Research and Development Tax Incentive) Bill 2019 and aim to strengthen the incentive, to ensure that Australia remains an attractive destination for investment in biopharmaceutical innovation.

That the Federal Government expand the JobKeeper payment eligibility criteria to include pre-revenue biotech and medtech companies working in Australia, as these companies are a critical part of the ecosystem and house priceless talent and intellectual property that could be permanently lost to Australia if they are not able to weather the COVID-19 storm.

4. Adopting critical health learnings and new efficiencies from the COVID-19 health response

The focus on the supply chain has opened up opportunities to modernise and improve supply chain efficiencies and delivery methods. It has been 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).

Visibility of supplies will enable transparent and accurate information to be provided directly to patients on where to find their medicines if there are local stock outs.

We also need to be mindful that even out of lockdown, without a vaccine, there will still be elderly, vulnerable and immunosuppressed patient populations that will need these mechanisms in place to ensure their own health safety.

Involving the patient/carer's experiences, together with healthcare professional community views, will be essential in the evolution of our medicine supply processes. This is the opportunity to modernise our medicine supply chain to meet current and future needs of patients and consumers.

As noted earlier, Medicines Australia hosted a consumer round table of some 16 consumer and patient organisations, with participation from the TGA and a facilitated discussion by Consumer Health Forum around the complexities of the medicines and vaccines supply chains. The roundtable identified a number of issues in terms of effective communication to consumers regarding stock shortages and stock-outs:

- The need for more effective ways to proactively communicate to consumers with advanced warning of stock shortages or stock-outs prior, rather than just the reliance of the TGA website and at pharmacy level
- Continued public health messaging around the importance of not stock piling and panic buying of medicines, particularly over the counter medicines
- Defining and proposing a national mechanism to support patients in what they need to do to get access to medicines if there is a stock-out issue
- Opportunity for Physicians to be more aware of potential stock shortages and stock-outs and effectively communicate this with patients

Recommendations:

Supply Chain:

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

That the Federal Government, for the purposes of national supply management:

a. work with Medicines Australia to consider policy options to encourage greater supply chain redundancy and stock levels for identified/agreed products of clinical significance
b. introduce national coordination of medicines supplies at all health levels including hospitals, States and Territories, to agree safe and equitable distribution during crisis
c. ensure dispensing is appropriate to manage supplies at all times, but particularly during times of crisis
d. ensure effective communication to consumers regarding stock shortages and stock-outs with advanced warning of stock shortages or stock-outs, rather than just the reliance on the TGA website and at pharmacy level
e. establish a national mechanism to support patients in what they need to do to get access to medicines if there is a stock-out issue

Patient Focus:

That the Federal Government:

a. Continue ongoing use of Telehealth, E-prescribing and Home Delivery of medicines beyond September, as an additional mechanism beyond face to face healthcare delivery.
b. Incorporate the 'voice of the patient' in the matters of healthcare and utilise consumer expertise and expectations in policy decision making
c. Promote the use of remote monitoring in clinical trials to ensure remote and rural patients have equal access compared to urban patients.

Conclusion

A purposeful and collaborative health response has been critical with the COVID-19 pandemic – to manage the emergency itself while also give genuine, active support and solutions to manage the community's overall health.

This has been one of the key lessons learnt from the pandemic – the importance of collaboration.

Other key lessons have been:

- the value which the community places on health
- the need to continually educate consumers on the importance of maintaining their health
- the pace with which great advances have been achieved in a short period of time and the value of such innovation – telehealth has been implemented in days, not years; and
- the critical link between the nation's overall health and economic wealth.

Prioritising and investing in innovative and advanced health strategies, together with the scientific community, will help to build a purposeful economic recovery and future proof Australia.