



MTPConnect COVID-19 Impact Report

The Impact of COVID-19 on the Australian Medical Technology, Biotechnology & Pharmaceutical Sector

June 2020



Acknowledgments

This COVID-19 impact report was developed with input from over 80 senior sector executives, through an online survey and targeted stakeholder consultations. The perspectives shared by these senior stakeholders from industry associations, companies, regulatory bodies, research organisations, government representatives and funders have informed key insights, themes, stories and recommendations within this report. A special thanks to the Medical Technology Association of Australia for its contribution to producing the supplementary report to this Impact Report. The list of stakeholders consulted through interviews is shown in the table below.

List of senior sector stakeholders consulted

Name	Organisation	Name	Organisation
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Bronwyn Le Grice	ANDHealth	Sue MacLeman	MTPConnect
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Lorraine Chiroiu	AusBiotech	Alex Fowkes	MTPConnect
Dr Chris Nave	Brandon Capital Partners	Julie Phillips	MTPConnect
Brooke O'Rourke	Cochlear	Dr Douglas Robertson	MTPConnect
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Mandie Lammens	Grey Innovation	Adjunct Professor John Skerritt	Department of Health (TGA)
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1. Overview of the COVID-19 pandemic

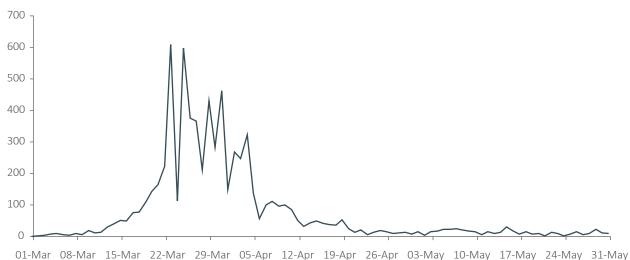
Australia's first case of novel coronavirus (SARS-CoV-2) infection was confirmed by authorities in Victoria on 25 January 2020. The patient, who arrived in Melbourne on 19 January, was from Wuhan, China where the pandemic is believed to have originated in November 2019.

The outbreak was declared a Public Health Emergency of International Concern by the World Health Organization (WHO) on 30 January and the infectious disease caused by SARS-CoV-2 was formally named COVID-19 on 11 February. A month later, on 11 March, COVID-19 was formally declared a pandemic by the WHO.

Globally, more than 6 million cases and 375,000 deaths have been reported since the beginning of the outbreak in November 2019 to the end of May 2020. These figures are believed to be understated, as countries are not consistent in the manner in which they report cases and deaths¹. At the time of writing this review, Belgium, Spain, Italy, United Kingdom and France have suffered from the highest rate of lives lost, per million of population². Total active cases reported as of the 31 May are the highest in United States of America (1.8 million), Brazil (0.5 million) and Russia (0.4 million).

In Australia, after a sharp rise in new COVID-19 cases during the month of March, the curve was subsequently 'flattened' and the number of cases has stabilised at around 7,200, with 103 people losing their lives to COVID 19. Australia's apparent success in managing the first wave of infections is in large part due to the swift and decisive actions to implement social distancing measures, targeted regulations, intergovernmental cooperation and a strong focus on testing. Compared to other nations, Australia's COVID-19 experience is considered a success and from an epidemiology perspective, the outcomes have been more positive than first predicted.





Source: World Health Organisation

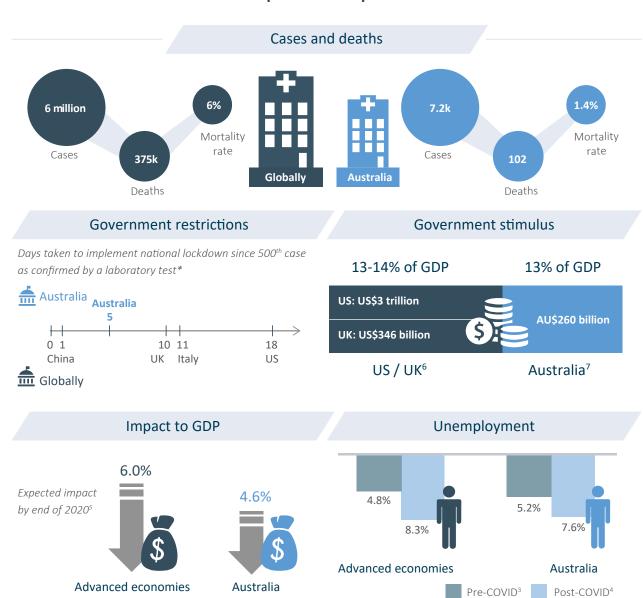
¹ Hien Lau and Veria Khosrawipour, Internationally lost COVID-19 cases, Journal of Microbiology, Immunology and Infection, 14 March 2020

² Coronavirus (COVID-19) deaths worldwide per one million population, Statista and Johns Hopkins University, May 20 2020



The Australian government has also responded to mitigate the impact of the COVID-19 pandemic on the economy with a mixture of fiscal stimulus, employer, employee and sector-specific support packages. JobKeeper, asset write-offs, SME cash flow assistance and payment deferrals are some of the support mechanisms that have been implemented. Further details can be found in Appendix 2.

Global and Australia COVID-19 impact and responses



Note: * Some countries did not have laboratory tests in place at scale as early as Australia



Cases and deaths

- Globally, we have seen 6 million cases, and 375,000 deaths, indicating a mortality rate of 6% of reported cases
- Australia has seen 7,200 cases, and 103 deaths, indicating a mortality rate of 1.4%

Government restrictions

- Major countries, like Italy, United Kingdom and the United States, imposed restrictions between 10, 11 and 18 days, respectively, after recording their 500th case. China implemented their lockdown the very next day
- Australia imposed localised lockdowns 5 days after the 500th reported case

Unemployment

- The combined unemployment rate in 2020 for all advanced economies as measured by the International Monetary Fund (IMF) is projected to be 8.3% as at 6 April 2020, compared to pre-COVID levels of 4.8%³
- Unemployment levels in Australia were steady at 5.2% in February, and since COVID-19 impacted the nation, unemployment grew to 7.6% in May with latest estimates forecasting the unemployment rate to be in the order of 8% in September 2020⁴

Impact on GDP

- As of April 2020, the IMF predicts the world's advanced economies will experience a 6.1% drop in annual GDP (real) by the end of 2020⁵
- In contrast, Australia is expected to see a 4.6% drop in annual GDP (real)

Government stimulus funding

- To date, the US and UK have committed US\$3 trillion (14% of GDP) and US\$346 billion (13% of GDP)⁶ respectively, to support their local economies, which may further increase in the near to medium term
- As of 1 June 2020, the Australian Government has promised to provide AU\$260 billion in financial support for the Australian economy which is 13% of national GDP⁷

While the number of cases and lives lost in this first wave of the COVID-19 pandemic has been much lower than predicted, the full impact of COVID-19 on the Australian economy and MTP sector may not be realised for many months. As restrictions on businesses and social distancing measures put in place

³ International Monetary Fund, Unemployment rate: advanced economies and Australia, April 2020

⁴ Matthew Cranston, Treasury sees a faster economic recovery, Australian Financial Review, 9 June 2020

International Monetary Fund, World Economic Outlook April 2020: The Great Lockdown, April 6 2020

Stephanie Segal and Dylan Gerstel, Breaking down the G20 Covid-19 Fiscal Response, Center for Strategic and International Studies, 30 April 2020

⁷ Treasury, Economic response to the Coronavirus, 26 May 2020



to minimise the transmission of the virus are slowly eased, there is considerable uncertainty regarding how the economy will perform as government support programs, such as JobKeeper, are wound back and there is the ever-present potential for new waves of infection to eventuate.

As the Growth Centre for Australia's medical technology, biotechnology and pharmaceutical (MTP) sector, MTPConnect has been closely monitoring the impacts of COVID-19 on Australia's MTP sector. Through a series of reports, MTPConnect will explore these impacts in detail and provide timely, valuable and verifiable information for the community, MTP sector participants and government to inform actions to rebuild and sustain the sector and the jobs it supports.

This first report covers the four-month period from February to May 2020. It outlines the impacts of the COVID-19 pandemic felt by organisations across the different parts of the MTP value chain, highlights how companies have responded to the COVID-19 crisis and discusses the path to recovery and emerging lessons learned from the collective experience of the sector to-date. In developing this report, input was gathered from over 80 senior executives (CEOs, COOs, Department Heads and other leaders) across the MTP sector. This included direct interviews with senior executives in addition to a targeted pulse survey with 17 questions that MTPConnect distributed. A more detailed description of the methodology used to develop this report can be found in Appendix 3.



2. Assessment of COVID impact on MTP sector

Introduction to the MTP sector in Australia

The most recent Sector Competitiveness Plan published by MTPConnect in April 2020 reported that the sector had continued strong growth on a range of metrics, contributing \$5 billion in Gross Value Added (GVA) to the Australian economy and accounting for 68,000 Australian jobs in 2019 - prior to the COVID-19 pandemic⁸. It is an innovative and vibrant sector that has given the world the heart pacemaker, the bionic ear, the cervical cancer vaccine, 3D printed titanium implants, the continuous positive airway pressure (CPAP) devices for sleep apnoea, and innovations like the nanopatch for needleless vaccine delivery and even Wi-Fi to enable digital health solutions.

The MTP value chain encompasses a diverse range of participants, each playing a critical role in the sector's growth and success. This value chain comprises consumers and patients, universities, other research organisations, small and large local and multinational companies, investors, service providers, industry organisations, infrastructure providers, governments, regulators, policymakers, funders, clinicians and others involved in healthcare delivery, such as state health departments and private medical practice. The MTP sector has been on the front line for research, diagnosis, management, prevention and treatment of infectious diseases and has played a critical role in driving Australia's COVID-19 response.

This chapter describes the overall impact COVID-19 restrictions have had on the MTP sector, up until the end of May 2020. The impacts on each sub-sector, including pharma and biotech, medtech and digital health, research institutions, government, service providers and funders, are outlined as well.

Assessment of overall sector impact

The COVID-19 crisis has had a strongly negative impact on the MTP sector, as it has many other parts of the Australian economy. Sector executives and senior leaders rated the overall impact on their businesses as 2.5 on a scale of 1 to 7, where a rating of 1 is a highly negative impact and 7 is highly positive.

Commercial activity across the sector, as measured by the market capitalisation of ASX-listed MTP companies has fallen \$11 billion (or 5%) from \$211 billion in February 2020 to \$200 billion in May 2020. While this decline is lower than the corresponding 24% decline of the S&P / ASX All Ordinaries index over the same period, it is primarily driven by the steady market capitalisations of CSL and ResMed, two companies that have both played significant roles in responding to COVID-19 by trying to develop vaccines / therapeutics and medical devices, respectively. Excluding these two companies from the analysis reveals the rest of the Australian sector has experienced nearly a 16% decline in market capitalisation, akin to the S&P / ASX index over the same period.

However, it is important to move beyond averages and consider the impact across different organisation types in order to fully understand the impact. The sector has a vast array of organisation types engaging in a range of activities and the impact has varied significantly. Some companies, such as those providing COVID-19 related supplies such as ventilators and ICU equipment, have experienced an increase in activity or demand for products. Others for whom demand for their products / services depend on elective medical surgeries have faced a drastic reduction in demand to such an extent that the ongoing viability of those organisations is under threat.

⁸ MTPConnect Sector Competitiveness Plan April 2020





Note: *Last price as at 1 May 2020; ^Each segment in the chart has been indexed to 100 for their relevant market capitalisation as at 1 June 2019 Source: Thomson Reuters Datastream: L.E.K. analysis

Three main underlying factors have driven the level of impact felt by organisations across the MTP sector; value chain focus, size of organisation and alignment to COVID-19 needs.

Value chain focus

The impact of COVID-19 has varied depending on the part(s) of the MTP value chain that an organisation is focused; basic research, pre-clinical research and development (R&D), clinical trials, manufacturing, sales and distribution. Organisations with a greater emphasis on early-stage research and pre-clinical R&D have been more negatively impacted than those with a greater focus on later-stage clinical trials and commercial activities. Based on responses to the pulse survey, 73% of organisations involved in basic research and 69% of organisations engaged in pre-clinical trials reported moderate to high negative impacts. 58% of organisations involved in clinical development and 63% of organisations involved in manufacturing reported moderate to high negative impacts, though further one-on-one interviews with senior sector executives suggest the impact on clinical development has been more significant which will be discussed further in this report. This is a function of the different operating constraints experienced to meet social distancing requirements and to free up capacity in hospitals, as well as the scale and level of diversification of an organisation, which we discuss later in this section. Lockdown and social distancing measures across Australia have limited the ability of workers to work on-site and physically continue R&D activities in laboratories9. In contrast, manufacturing operations, particularly in the pharma / biotech and medtech sub-sectors, were widely deemed essential services and continued to operate, albeit with stricter social distancing and hygiene guidelines. Many commercial operations present in later stage organisations such as marketing, sales and medical affairs were able to continue, albeit with some restrictions in place.

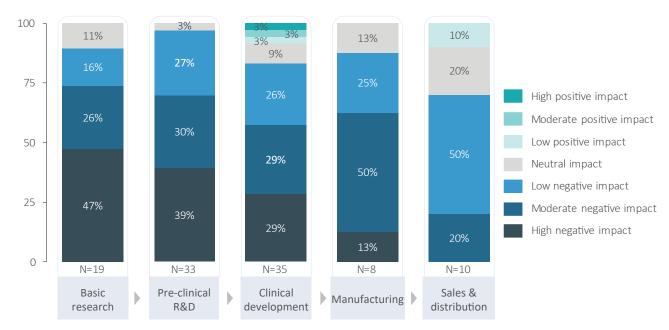
Frank Larkins, Impact of the pandemic on Australia's research workforce, Rapid Research Information Forum, 6 May 2020





Impact of COVID-19, by position in the value chainPercent of sub-sector respondents

(N=47)



Question: Q5. In which parts of the value chain does your organisation operate? (Select all that apply); Q7. How would you describe the overall impact of the COVID-19 pandemic on the level of activity for your organisation when compared to normal operating activity?

Source: L.E.K. Pulse Survey 2020

Size of organisation

Pandemic impacts on organisations have also varied by the size of the organisation. Smaller organisations, in terms of employees or annual revenue, have been more negatively impacted compared to larger organisations. Our survey results indicate that 49% of small companies have suffered a moderate to high negative impact, as opposed to 17% of large companies¹⁰. This is likely explained by the fact that larger companies have more significant cash reserves to withstand the impact of a revenue slow-down compared to smaller companies. Additionally, many larger organisations have benefited from diversified operations, for example, continued demand and revenue for products in some parts of their business while facing reduced demand in other areas. Smaller companies, particularly start-ups and early-stage biotech / medtech / digital health companies, were further disadvantaged if they were pre-revenue as these organisations have not been eligible for JobKeeper payments from the Federal Government.

Alignment to COVID-19 needs

A differentiating factor of the MTP sector compared to others in the Australia economy is that many organisations have played a direct role in responding to the COVID-19 crisis, including developing ventilators, vaccines and therapeutics against SARS-CoV-2 and producing and sourcing vital medical supplies and protective equipment for healthcare workers. Consequently, the impact on organisations has

Note: Moderate and high negative impact (corresponding to a rating of 1 or 2 on a scale of 1 to 7 where 1 is a high negative impact) classified by respondents in our survey

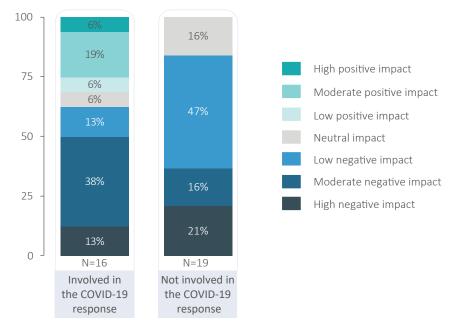


varied depending on whether their products and capabilities have been aligned to COVID-19 crisis needs. Our survey analysis suggests that 21% of companies who were not aligned with the COVID-19 response experienced high negative impacts compared to 13% of companies who were aligned. For example, pharma / biotech, medtech and research organisations working on infectious disease and respiratory disease therapeutic areas such as CSL, ResMed and CSIRO have successfully pivoted resources to support further research and development of COVID-related products and therapies.

Pharma companies have benefited from increased demand for medicines driven by consumers stockpiling during the crisis. Dispensing of some medications, such as antibiotics and respiratory drugs in the period March to May 2020 increased by 100% versus the same period last year¹¹. In contrast, organisations whose products / capabilities were not aligned to COVID-19 saw a decline in activity. However, this panic buying behaviour has resulted in an increase from 460 to 590 medicines shortages (a 26% increase) in the period from March to May 2020 versus the same period last year. It should also be noted that while pharmaceutical companies benefited from the short-term increase in demand for medicines, they have also incurred significantly increased costs to serve this demand due to increased supply chain costs (e.g. increased cost of air and sea freight). In addition, companies are also likely to see demand for their medicines fall in the medium term due to consumers gradually using their stockpiles, creating a delay in when they next purchase, due to a "pull-forward" rather than net increase in demand.



Impact of COVID-19 on MTP sector companies, by involvement in the COVID response Percent of segment respondents (N=35)



Note: Excludes research institutes

Question: Q1. What type of organisation do you work for?; Q7. How would you describe the overall impact of the COVID-19 pandemic on the level of activity for your organisation when compared to normal operating activity?; Q12. Has your company been involved in directly supporting the COVID-19 response, and if so, how?

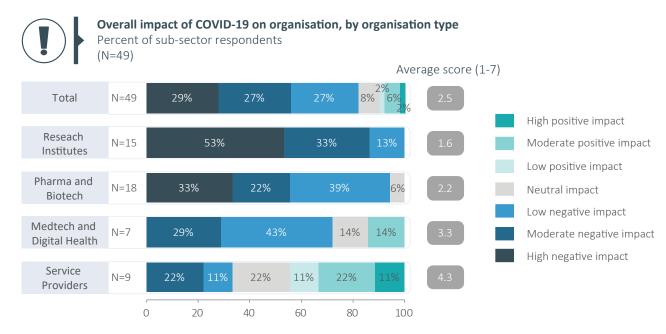
Source: L.E.K. Pulse Survey 2020

¹¹ Senior stakeholder interview with international pharmaceutical company



In-depth analysis of impacts on MTP sub-sectors

In this section, we will highlight the impact of the pandemic on the key sub-sectors within the MTP sector; pharma and biotech, medtech and digital health, research institutions and other organisations such as service providers, government agencies and funding organisations. The survey results outlined below highlight the differences in how the sub-sectors have been impacted, with research institutes and the pharma and biotech sub-sectors impacted more negatively than medtech and service providers, with average scores of 1.6 and 2.2 out of 7 point scale respectively (where 1 is the highest negative impact rating). As mentioned previously, the overall impact across all sub-sectors has, on average, been strongly negative with a score of 2.5.



Question: Q1. What type of organisation do you work for?; Q7. How would you describe the overall impact of the COVID-19 pandemic on the level of activity for your organisation when compared to normal operating activity?

Source: L.E.K. Pulse Survey 2020

Pharma and Biotech companies

The most significant reported impacts of the COVID-19 crisis on large pharma and biotech companies have been:

- Inability to conduct existing clinical trials and source participants for new trials
- Delays to / lack of funding for new and on-going R&D efforts (typically smaller biotech organisations rather than large pharma)
- Supply chain challenges in sourcing critical input materials and facilities for R&D as well as commercial operations

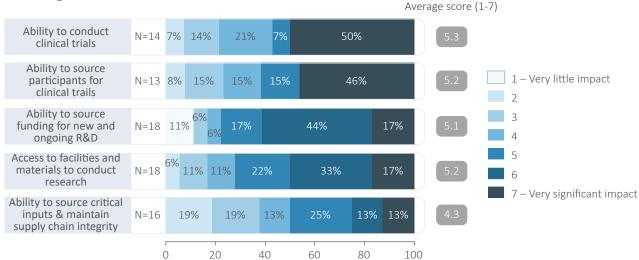
The diagram below illustrates the top five impacts reported by pharma / biotech executives surveyed and supports the observations above. It is noted that the responses contain a larger proportion of small biotech responses and therefore may skew towards research-related impacts.





Top impacts on Pharma and Biotech, by significance

Percent of respondents per impact (N=18)



Question: Q1. What type of organisation do you work for?; Q8. As a result of the COVID-19 outbreak, how would you rate each of the following in terms of their impact on your business? (Please rate each these below on a scale of 1 to 7 where '1' means "very little impact" and '7' means "very significant impact")

Source: L.E.K. Pulse Survey 2020

Impact on clinical trials

The various lockdown measures and social distancing requirements imposed on hospitals and patients made it challenging to continue operating current clinical trials. Nearly 60% of our survey respondents indicated that their ability to conduct clinical trials was very significantly impacted. Critical clinical trials in areas such as oncology and those that were amenable to digital, virtual settings were able to continue during the pandemic. However, a large number of non-critical clinical trials – up to 90% of clinical trials run by some pharma companies - were put on hold as it was not practical to continue treating and monitoring patients. Concerns regarding patient safety, hospitals that stopped clinical trial monitoring activities or healthcare infrastructure being diverted for COVID-19 purposes were the common drivers of clinical trials being put on hold.

In addition, pharma and biotech companies found recruitment of patients for new clinical trials challenging as patients were not willing to participate in trials during this pandemic period. Approximately 55% of survey respondents indicated that new patient recruitment was significantly impacted due to the crisis. Some pharma and biotech companies consequently shelved plans for new patient recruitment and commencement of new clinical trials during March and April.



Impact on new and ongoing R&D

Biotech companies have also found it difficult to source funding for new and on-going R&D as a result of the pandemic. These delays can disrupt and delay years of planning as well as reduce the commercial attractiveness after years of investment as the sector has long development lead times of 10-15 years. Approximately 60% of survey respondents indicated that their ability to source funding was significantly impacted. Some funding organisations, such as the NHMRC, have delayed or cancelled certain grant funding rounds due to pandemic impacts on clinical trials and research¹². Also, restrictions on working in laboratories due to the lockdown measures and social distancing requirements have resulted in a slow-down of R&D activity in most areas of the sub-sector. The notable exception here is that R&D efforts directed towards the development of vaccines, diagnostic kits and therapeutics against SARS-CoV-2 have seen increased funding and levels of activity. Early-stage biotech firms have been disproportionately impacted by the slow-down by both their ineligibility to access JobKeeper and within R&D activity because this is often the primary focus of these companies. Early-stage biotech companies have had to focus on preserving cash during this period in which they have been unable to continue their research programs. This has significant implications for future cash reserves to complete clinical trials once they resume and the retention of jobs in the sector.

Impact on supply chains

The COVID-19 pandemic has resulted in a surge in demand for medicines as evidenced by a 45% increase in dispensing from pharmacies and a 100% increase in demand for respiratory products¹³. While this extra demand has primarily been due to consumers' panic buying behaviours rather than needs-based buying, it has caused significant stress on the supply chains of large pharma and biotech companies and wholesalers. Approximately 50% of survey respondents indicated that the ability to maintain supply chain integrity was significantly impacted. It has become increasingly challenging to source input materials and / or finished products from overseas given the dramatic decline in the sea and air freight services internationally, as well as the ability to export and move goods given border closures around the globe.

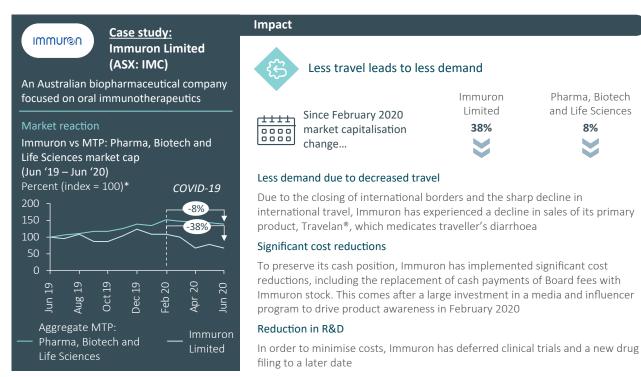
Pharma and biotech companies with manufacturing facilities in Australia such as CSL, GSK and AstraZeneca have diverse supply chains and redundancies built-in to be able to accommodate a pandemic. As a result, there was not a significant interruption to the ability to either export medicines to international markets or import medicines from offshore manufacturing. Pharma and medtech companies have incurred the additional cost of transporting freight via limited air, land and sea freight services to meet the urgent demand for products. For example, AstraZeneca Country President, Liz Chatwin, shared challenges sourcing space to move critical supplies in air freight. Air freight costs have increased between 3 to 10 fold during the pandemic compared to the typical pre-COVID costs. These costs have not been passed on to buyers due to the regulated prices of these products. Even with private market products, pharmaceutical companies have not been able to pass on the increase in costs to consumers. Domestically, the timely delivery of medicines to all regions of Australia has also required additional resource and capacity investment by pharmaceutical wholesalers such as API, Sigma and Symbion to distribute the higher volumes of medicines and to coordinate and address demand shortages in certain regions.

¹² NHRMC, Update – Changes to NHMRC 2020 funding schemes, 27 March 2020

¹³ Senior stakeholder interview with international pharmaceutical company



These impacts are illustrated by the case study below on Immuron, a small biotech focused on developing drugs for gut mediated diseases.



Note: *Market capitalisations as at 1 June 2019 have been indexed to 100 Source: Thomson Reuters Datastream: ASX: Immuron Ltd

Medtech and digital health companies

Medtech companies and digital health companies have experienced varied impacts, with the most significant impacts of the COVID-19 crisis on medtech and digital health companies being:

- change in demand for end-user products
- disruptions to the supply chain
- a reduction in operating cash flow, impacting the business sustainability

Change in demand for end-user products

Digital health and medtech companies involved in the COVID-19 response or whose products are perceived essential, including telehealth, have experienced increased activity levels and more positive financial outcomes than those who are not. Digital health companies surveyed by MTPConnect have experienced a positive impact on their businesses because social distancing regulations have led to a rapid and robust pivot towards virtual healthcare delivery, where virtual healthcare only accounted for less than 1% of all MBS funded attendances pre-COVID¹⁴.

¹⁴ Damien Angus, Maureen Connolly and Mariella Salita, The shift to virtual care in response to COVID-19, PwC, 9 April 2020





"The forced adoption of digital technologies has been a positive development, especially around e-prescriptions and telehealth. Rapid introduction of reimbursement was key, however this will need to be maintained and expanded to digital medicine and digital therapeutic technologies to fully capitalise on the full potential of our digital health sector."

— Bronwyn Le Grice, CEO and Managing Director, ANDHealth

Medtech companies whose products are involved in elective procedures and surgeries experienced a sharp decline in demand leading to challenging earnings this quarter. Cochlear hearing devices experienced an 80% decline in revenue across developed markets which is partially attributed to Australia's halt to elective surgeries from 25 March to 27 April 2020. Additionally, there has been a follow-on effect of a fall in the rate of new diagnoses for individuals requiring elective medical products as patients have opted to stay at home as evidenced by a sharp decline in tertiary care appointments¹⁵.

Disruptions to the supply chain

Gaining access to materials and maintaining supply chain integrity, including shipping from overseas sources has been a challenge for 70% of medtech companies who manufacture in Australia. The reduction in passenger flights and restrictions on sea freight has reduced the volume of goods that can be imported and exported. Several companies reported reaching out to government bodies and contacts for support to secure sufficient shipping space to ensure they could source critical medical goods, with the Taskforce and Working Groups under the Health Industry Coordination Group and Austrade being most commonly cited.



"We had to reach out to the Department of Foreign Affairs to organise supply"

— James Doyle, Lead, MTAA Ventilator Workstream & Senior Director – Commercial & Public Affairs, Stryker

As mentioned previously, reduction in international freight volumes has meant that freight costs have increased by up to 3 to 10 fold when compared to pre-COVID-19 costs. Even medtech companies who have had increased demand for their products have suffered from lower margins due to increased freight costs during the pandemic. For companies who have suffered a drop in product demand, the increase in shipping cost has compounded the financial impact as they suffer from lower revenue and lower margins.

A reduction in operating cash flow, impacting business sustainability

Medtech companies have had challenges managing their cash flows. This has been partially due to delays in payments for outstanding invoices, as hospitals and other care facilities were taking longer and slowing their payment timeframes. A sharp decline in demand for products following the pause on most elective surgeries was also a contributing factor to cash flow constraints. Device companies exposed to the impact of elective surgeries such as Cochlear are reporting impacts including delayed product launches, repositioning lines of credit and using more financial instruments to sustain their company¹⁶. While JobKeeper has been an important policy to support employment, pre-revenue medtech entities

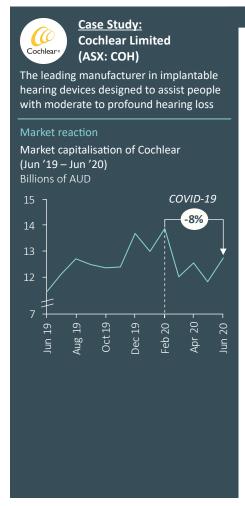
¹⁵ Maarten Ijzerman and Jon Emery, Is delayed cancer diagnosis a consequence of COVID-19?, Pursuit, University of Melbourne, 30 April 2020

¹⁶ Global Data, Coronavirus (COVID-19) Executive briefing, 27 April 2020



(like pre-revenue pharma / biotech companies) do not qualify for the support, leaving these companies exposed to significant job losses and financial pressure. Additionally, medtech companies intending to raise funds will likely face challenges given the volatile capital market. Our survey found that 57% of surveyed digital health and medtech companies have struggled to source funding for new or existing research and development as a result of COVID-19.

These three impacts are illustrated by the case study below on Cochlear, the leading, Australian-based hearing device manufacturer and exporter.



Impact



Reduced sales due to elective surgery restrictions

Decline in sales and bookings

To limit the spread of COVID-19, suspensions on elective surgeries have been enforced across the world, resulting in a c.80% decline in Cochlear implant unit sales for developed markets in April 2020. Additionally, social distancing restrictions are impairing the ability of clinics to see patients with a potential impact on the pipeline of future cochlear implant surgeries in the short term. This is being compounded by uncertainty in patients around the infection risks of COVID-19 that hospitals pose

"... There is a high level of uncertainty surrounding the impact of COVID-19 in terms of the extent and duration of the reduction in surgeries and the ability for recipients to access sound processor upgrades..."

— Dig Howitt, CEO, Cochlear

Prioritisation of R&D

Additionally, Cochlear has reprioritised some of its R&D spend in order to ensure that in the aftermath of the pandemic the research pipeline is in place, and it can hit the ground running. The reprioritisation of R&D has included accelerating emphasis on digital health and ways of providing care remotely, including the maintenance and programming of Cochlear devices remotely

Surviving the crisis

Cochlear has reduced production capacity, cut costs, raised capital, accessed government wage subsidies, and increased debt facilities in order to cope with the reduction in demand. These responses will be explored in more detail in Chapter 3

Note: *Last price as at 1 June 2020

Source: Thomson Reuters Datastream; ASX; Sydney Morning Herald



Research Institutions

Like pharma and biotech companies, the COVID-19 crisis has significantly impacted research institutions such as universities and medical research institutes. Impacts have included:

- inability to conduct clinical trials and source participants for new clinical trials
- difficulty in accessing facilities and materials to conduct research
- reduced access to funding for new and ongoing R&D efforts

The diagram below demonstrates the top four COVID-19 impacts, as reported by the research institutions surveyed.



Top impacts on Research Institutes, by significance

Percent of respondents per impact (N=15)



Question: Q1. What type of organisation do you work for?; Q8. As a result of the COVID-19 outbreak, how would you rate each of the following in terms of their impact on your business? (Please rate each these below on a scale of 1 to 7 where '1' means "very little impact" and '7' means "very significant impact")

Source: L.E.K. Pulse Survey 2020

Impact on clinical trials

Similar to pharma and biotech companies, over 50% of research institutions surveyed indicated they had been significantly impacted by their inability to progress current clinical trials and recruit participants to start new trials.



Impact on R&D activities

The lockdown measures and social distancing restrictions have also significantly impaired the ability of research institutions to maintain their levels of R&D activity. Staff who are not working in essential areas of R&D, such as infectious diseases, are largely limited in their ability to work in R&D laboratories¹⁷. Many research laboratories have therefore reduced their activity levels or shut down entirely. Further, international travel bans have disrupted the flow of international students and postdoctoral researchers, who comprise 37% of the workforce at research institutions and contribute to 26% of universities' operating revenues. For example, Sydney University expects a \$470 million loss due to COVID-19 and a 17% drop in international students this year¹⁸. The drop in international student numbers will impact universities for at least three years, and therefore limit their ability to cross-subsidise research using international student revenue.

Impact on funding

Though funding from public organisations such as the ARC, NHMRC and MRFF has continued, private donations, investments and the ability to fund research from internal surpluses have declined. Approximately 50% of survey respondents indicated their access to funding for R&D had been significantly impacted due to COVID-19¹⁹. For universities and MRIs, this reduction in income from other sources has severely impacted their ability to cover the overhead costs of conducting research which are not covered by government funding.

Major public funding organisations such as the ARC, NHMRC and MRFF announced some delays to their usual rounds of grant funding as they pivot their funding priorities to better support the national response to the COVID-19 pandemic. This has meant that some research programs have experienced delays in gaining access to funding for new projects and R&D activities. However, research activities that were directly correlated with the COVID-19 response (e.g. development of novel immunotherapies or vaccines for infectious diseases) experienced an increase in funding from public and private funding organisations and increased activity in laboratories. Examples of funding that has been provided in the past three months include \$2 million for future preparedness, \$3 million for mental health research, \$5 million for respiratory medicine, and \$8 million for antiviral development. MTPConnect launched a COVID-19 specific round of its MRFF-funded Biomedical Translation Bridge program in May 2020 to support the development of medical devices, diagnostics, prophylactics or therapeutic approaches in response to the pandemic.

The CSIRO is an example of an organisation that has been able to secure additional funding for R&D activities by pivoting its efforts towards researching COVID-19 vaccines. CSIRO's Health and Biosecurity unit successfully sourced \$2 million in funding from the Coalition for Epidemic Preparedness Innovation (CEPI) and \$11 million from the Australian Government to redouble its efforts in pre-clinical R&D related to the development of potential COVID-19 vaccines and therapeutic agents.

¹⁷ Alan Finkel, Rapid Research Information Forum: COVID-19 Research Workforce, Australian Academy of Science, 6 May 2020,

¹⁸ Jordan Baker, Sydney University expects a \$470m loss due to coronavirus crisis, Sydney Morning Herald, 8 April 2020

 $^{^{19}}$ Corresponding to ratings of 6 or 7 on a scale of 1 to 7 where 7 was very significantly impacted





Case study: Commonwealth Scientific and Industrial Research Organisation

Australia's national science and research agency with 5,500 staff across divisions.

Research across health focuses on coronavirus & infectious disease research, advanced medical diagnostics and devices, digital technologies for health and future science in health

Impact



Leading the charge on vaccination development

Increase in research related to COVID-19

Research activity at CSIRO's Health focus areas such as drug / vaccine development for infectious diseases, bioinformatics, and face mask manufacturing have increased significantly since Jan 2020. They were quick to move to vaccine development (within 2 weeks of identifying the need) due to having in place a team, capabilities and infrastructure that was developed 4 years ago. They have since collaborated with the University of Queensland, Oxford University and Inovio Pharmaceuticals to develop and test COVID-19 candidates

"...Our BioInfomatics team is looking at the genome sequencing of the virus...We're also looking at the health effects of the lockdown...on the dietary and physical behaviours of consumers..."

— Rob Grenfell, Health Director, Health & Biosecurity, CSIRO

New funding for vaccine development

CSIRO has now received funding from the Coalition for Epidemic Preparedness (CEPI), the Australian and Queensland governments, and the Paul Ramsay Foundation to support its three vaccine R&D and drug development efforts

Redeployment of CSIRO Workforce

Personnel from other research areas have been redeployed to support CSIRO's COVID-19 response efforts. There are now c.120 staff working at CSIRO's Australian Centre for Disease Preparedness, incl. 30 PC4 level staff, up from c.15 staff prior to the COVID-19 pandemic

Reductions to infrastructure access

In addition to biosecurity protocols, infrastructure has been strictly restricted to properly trained personnel working on live COVID-19 agents to ensure the safety of workers. Typical research facilities only operate at PC3 level instead of the PC4 level used for COVID-19 work

Other organisations

MTP service providers like CROs, government agencies and funding organisations have seen their activities significantly impacted in different ways due to the COVID-19 pandemic.

Government agencies

Government agencies and regulators such as the Department of Industry, Science, Energy and Resources (DISER), the Department of Health (DoH), Department of Foreign Affairs and Trade (DFAT), Austrade, Department of Defence and the Therapeutic Goods Administration (TGA) have seen the following key impacts due to COVID-19. First, they have been required to pivot their resources and efforts to support the pandemic and they have held direct responsibility for portions of the response²⁰. Second, they

MTPConnect and MTAA, Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19, June 2020



have had to significantly increase the pace and responsiveness of their work as the rapidly evolving nature of the pandemic has necessitated quick turnaround times for the creation and execution of various taskforces and working groups responding to the crisis, evaluation and approval of new medical devices. Third, government agencies and regulators have also seen their core roles change during the crisis — shifting from a traditional, policymaking one where their role is mainly transactional to a more collaborative, advisory role where they are more closely involved with key stakeholders in the private and public sector. The case study below details how one government agency, the TGA, has been impacted and how they have responded.

Case study:



The TGA is Australia's regulatory body for therapeutic goods

As the regulatory body for Australia, the organisation regulates: medicines available in supermarkets / pharmacies or prescribed by doctors / dentists, medical devices, diagnostic test products and vaccines, blood products and other biologics

Impact



Rapid assessment and more advisory

Increased need for rapid assessment

Need for faster assessment and turnaround times has increased. Organisations seeking advice, assessments or approvals from the TGA have been seeking faster responses from the TGA in order to enable rapid supply of products and solutions during the uncertain and rapidly evolving COVID-19 environment

For example, companies who have not had previous experience with medical products have required rapid advice on regulatory requirements and help to understand and provide the necessary evidence for the TGA assessment processes for manufacturing, producing or supplying products

Consequently, TGA has prioritised and fast-tracked certain medical products – see Chapter 3

Increased requirement for more advisory role and services

Requests for advice on what and how products are regulated have increased significantly, including from companies who have not had previous experience with medical products. As mentioned in the MTAA / MTPConnect Taskforce Paper, over 2,200 new manufacturers entered the market between February and April. This advisory role has challenged TGA's cost-recovery model to ensure organisations were provided with accurate and rapid advice during the pandemic. Consequently, the TGA has also had to develop simplified communication of its guidelines and processes in order to assist these inexperienced organisations, as well as other stakeholder supporting the COVID response

"... We have had to place a greater emphasis for hand-holding and advisory services for organisations. We had over 100 people during March and April providing COVID-19 related advice and guidance ..."

Adjunct Professor John Skerritt, Deputy Secretary, Health Products
 Regulation Group, TGA, 12/05/20

Stockpiling causing medicines shortages

Medicines shortages have increased 26% since 1 March 2020, though the impact has primarily been driven by stockpiling and panic buying by consumers

As we will illustrate in the Responses chapter, the TGA has played a major role in coordinating the various participants across the sector to better manage availability of medicines in order to minimise impact on patient health and wellbeing



Funding organisations

As we have discussed in previous sections, funding organisations such as the ARC, NHMRC and MRFF have pivoted their funding priorities during the pandemic to better support responses to the crisis, resulting in \$18 million of newly introduced funds for COVID-19. In addition, market uncertainty, severe fluctuations in demand and the way organisations are operating has made it a challenging environment for venture capital firms to both deploy capital to support new ventures as well as exit investments.



"... investment capital [is] rapidly drying up from traditional sources like high net worth individuals and super funds, [which] means many early-stage companies that could be the next CSL or ResMed might not make it."²¹

— Chris Nave, Founding Partner and Managing Director, Brandon Capital Partners

Service providers

The impact felt on service providers has been primarily linked to the parts of the sector they are servicing. MTP sector service providers like contract research and manufacturing organisations have generally felt more moderate impact due to COVID-19 than other sub-sectors. The ability of these organisations to pivot their efforts to activities that support the COVID-19 response has helped mitigate the effects on their businesses. For example, Planet Innovation has seen an increase in demand for their contract manufacturing as companies seek additional, diversified manufacturing capability to help maintain their supply chain integrity.



"We've [Planet Innovation] just won a contract for a product that was developed in the US, is manufactured in the US, and now they're looking for a second source of manufacturing, a dual-source so that their company has supply chain resilience."²²

- Stuart Elliott, Co-CEO, Planet Innovation, April 2020

Others who have not been able to pivot their activities and projects towards COVID-19 responses, or fully offset declines elsewhere in their businesses, have seen their activities negatively impacted. These impacts were driven by the slow-down in clinical trials activity and cost containment measures that were implemented at most pharma, biotech and medtech companies. Typical clients of some service providers (e.g. advisory and consulting organisations) have reduced their expenditure on these activities to better manage their cash flow and maintain the financial sustainability of their respective organisations.

In summary, the COVID-19 pandemic has affected all MTP sector organisations in varying ways, many negatively and, as a result of the sector's work to directly support pandemic responses, some with positive activity. It has driven new situations, requiring a variety of responses. The following chapter outlines these responses.

²¹ Carrie LaFrenz, Biotechs face 'generational loss' without JobKeeper, Australian Financial Review, 25 May 2020

²² Stuart Elliott, Planet Innovation speaks about manufacturing supply chain resilience, April 2020



3. MTP sector responses to the COVID-19 pandemic

The pandemic escalation period in Australia from March to April was characterised by unprecedented uncertainty and the need for businesses to respond and adapt in a rapid manner to protect staff and customers, provide support to the COVID-19 response and in some cases to simply "survive".

Through discussions with senior executives and leaders in the industry, organisation responses have typically fallen into one of four categories linked to the extent to which the organisation was impacted, and whether opportunities have existed to pivot and support the COVID-19 response:

- Immersion in the COVID-19 response: Those organisations experiencing a significant surge in demand for products and / or services have needed to align and adapt to support the national response to the COVID-19 pandemic
- Pivoting to support COVID-19: Organisations with some assets and capabilities to support the COVID-19 response have rapidly pivoted a proportion of organisation activities and resources to address needs arising from COVID-19
- **Protecting organisation viability and sustainability:** Those organisations facing significant negative economic impacts of COVID-19 have focused on preserving financial sustainability and viability
- Continuing operations while observing distancing requirements and constraints: Those
 organisations that have a modest financial impact but have had to adapt operations to meet
 distancing requirements distancing requirements

Most notable was the collaboration between industry and government to ensure the supply of vital medical equipment under the Health Industry Coordination Group chaired by Glenys Beauchamp PSM. The industry stepped in to fulfil manufacturing and procurement needs; this collaboration was in an unprecedented manner leading to the securement and production of vital medical equipment within Australia. The details of this collaborative effort are presented in the Supplementary Report²³.

The table below summarises these four categories of responses and the following section further illustrates these responses.

All companies who provided input into this report noted that their first priority was and has been the safety and health of employees, customers and the broader Australian public. This has guided their responses and actions. Meeting social distancing requirements has been a universal action taken by organisations in the sector.

²³ MTPConnect and MTAA, Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19, June 2020



Types of responses

Segment	Description	Example organisations (products / services)	Illustrative actions taken by organisations
Immersion in the COVID-19 response	A number of pharma / biotech, medtech and digital health companies have seen a surge in demand for their usual products and / or services during the COVID-19 period because these products / services have been essential for consumers, healthcare organisations and / or governments to address the health impacts of COVID-19	ResMed, notus industry consortium, (ventilators), Med-Con (PPE such as face masks), telehealth companies (MedAdvisor, Coviu), Government agencies such as the TGA, DoH	Ramped-up production and distribution of products / services seeing increased demand either on their own or in collaboration with other competitors Secured alternative supply chain solutions often involving higher than normal cost of freight / logistics to serve the increased demand Increased workforce capability to serve the increased demand
Pivoting to support the COVID-19 response	Organisations that have deployed a sub-set of their capabilities to support demand for services and products to support	Alcohol producers developing hand sanitisers, Stryker, CSL, DetMold (masks), Clets Linen (gowns) CSIRO, Planet Innovation, TGA	Redeployed staff, facilities and resources to develop and / or voluntarily provided services that aid the national response to the COVID-19 crisis Reprioritised R&D efforts to focus more on addressing challenges presented by COVID-19 impact Implemented rapidly with a more responsive pace of working internally in order better to navigate the rapidly evolving nature of the pandemic
Protecting organisation viability and sustainability	Organisations that have experienced a significant drop in demand for their products / services due to the COVID-19 pandemic and have been unable to pivot their activities sufficiently to mitigate this decline in demand	Cochlear, small biotechs, such as Immuron, Universities and MRIs	Used cost saving tactics and sought aid to best manage the decline in demand to ensure on-going survival
Continuing operations while observing distancing requirements and constraints	MTP sector organisations that have been minimally impacted by the COVID-19 pandemic because the pandemic did not severely impact demand for their products / services	There are relatively few organisations that fall into this category due to the nature of the impact on the sector. E.g. some service providers such as IP advisors, market access advisors are unlikely to have experienced a significant impact in this period beyond the need to adapt operations to social distancing	Minimal impact on overall business with impacts typically limited to particular products or business lines (e.g. R&D and sales functions) Largely maintained the course with organisation activities, while adjusting to the COVID-19 restrictions



A surge in demand for products / services due to COVID-19

The pandemic has resulted in a surge in end-user demand for specific medicines, medical devices and services. For instance, as the number of COVID-19 cases rose exponentially in March, demand for vital medical equipment required to treat these patients such as ventilators, ICU monitors and equipment escalated. Consumers' panic buying behaviour meant medicines for respiratory conditions such as salbutamol saw demand reach levels two times pre-COVID levels.

MTP sector organisations who had such products / services (e.g. ResMed, notus, Med-Con) benefited from this surge in demand. Their primary responses have been as follows:

- ramped-up production and distribution of products / services seeing increased demand either on their own or in collaboration with other competitors
- sourced alternative supply chain solutions often involving higher than normal cost of freight / logistics in order to serve increased demand
- increased workforce capability to serve the increased demand

Ramped up production to meet demand surge

To meet the rapid increase in demand for products and services, organisations such as Stryker, Grey Innovation, Med-con, ResMed and PTA had to find ways to increase production capabilities. Companies such as Med-con, with support from the Australian Government, contracted additional machinery to increase their manufacturing capabilities and capacity to hit their target of 50 million masks produced every six months²⁴. Companies such as Coviu and MedAdvisor are managing the surge to telehealth services, aided by \$699 million in government funding committed for telehealth services over six months²⁵. Coviu CEO, Silvia Pfeiffer observed that video consults on their software increased from 300 per day to 10,000 in a week in the space of a fortnight²⁶. Ego Pharmaceuticals also ramped up production. They doubled their operating hours, working around the clock, and produced four times as much sanitiser than pre-COVID levels in order to meet the surge in demand²⁷.

Sourced alternative supply chain solutions

During this period, organisations sourcing critical components to build ventilators competed with companies and countries around the world for supplies. Planet Innovation was approached by several companies looking to build in redundancies and secure domestic manufacturing capabilities, both in Australia and the USA. The DoH initially tried to increase procurement from China for pathology tests and PPE, however it became clear that in order to confidently meet demand, local sourcing should be either stood-up or expanded. Participants in the Health Industry Coordination Group's Taskforce initiative, including senior representatives from government and industry, leveraged their networks to source critical components and solve supply chain interruptions to meet both Federal and State government medical stockpile needs.

²⁴ Tom McIlroy, 'Tiger team' ready to export ventilators to aid COVID-19 fight, Australian Financial Review, 5 May 2020

²⁵ Rachel Williamson, Investors can't get enough of telehealth as global funding surges in Q3, Stockhead, 16 April 2020

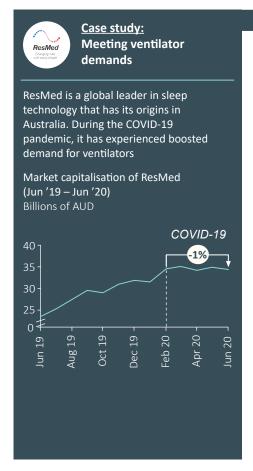
²⁶ Rachel Williamson, Call the midwife: Telehealth has arrived', Stockhead, 29 March 2020

²⁷ Paul Sakkal, All go at hand sanitizer factory amid a crisis 'bigger than Ben-Hur', The Age, 27 February 2020



Increased workforce capability to service the demand

To support the influx of activities, staff were sourced from new locations, such as internally from other parts of organisations and from manufacturing sites that were being stood down. Face mask producer Med-con hired 40 new staff and even had the Australian Defence Force provide additional resource support²⁸. Grey Innovation notably brought on 22 more staff members to support a ventilator production increase. The TGA redirected nearly 100 staff members to support the COVID-19 surge in demand and advisory needs. For digital health platform MedAdvisor, this included a fast track of their platform to offer pharmacy delivery at the end of March which, "kicked us on five-plus years when it comes to digital health adoption" said MedAdvisor founder, Robert Read²⁹.



Note: *Last price as at 1 June 2020 Source: Thomson Reuters Datastream; ASX

Responses



Ramped up production

ResMed produced 52,000 ventilators during the March quarter, representing a three-fold increase on normal production

The sharp increase in production is expected to continue and ResMed is preparing for sales to last well beyond the end of the 2020 financial year

Due to social distancing restrictions, however, there has been a reduction in diagnoses of sleep apnea and therefore demand for ResMed's sleep apnea devices

"... the group is ready to supply ventilators amid any future waves from the coronavirus..."

— ResMed, AFR, May 2020



Supply chain solutions

Due to global supply chain disruption, input supplies for higher-end ventilators have been constrained, putting upward pressure on prices. This may be the reason why although ventilator sales increased, gross margins were 35bps below estimates

To overcome supply chain roadblocks, ResMed worked with government bodies to assist in the transport of parts

ff "... Industry Minister Karen Andrews got on top of the potential supply chain issues early and with energy..."

> — The Australian Manufacturing Forum, April 2020

²⁸ Senator the Hon Linda Reynolds CSC; The Hon Karen Andrews MP, Increasing domestic manufacturing during COVID-19, Joint Media Release, 17 March 2020

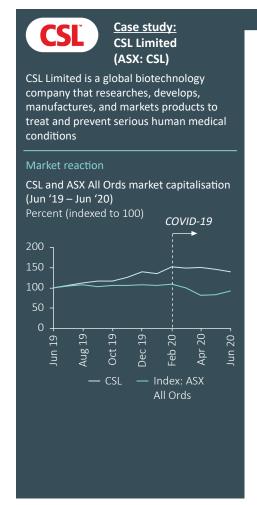
²⁹ Emma Koehn, Pharmacy players primed for drug home delivery booster shot, Sydney Morning Herald, 4 May 2020



Pivoting to support the COVID-19 response

The COVID-19 pandemic has presented significant opportunities for the development of new medicines, medical devices and services; from novel therapeutics and vaccines against SARS-CoV-2 to PPE like face shields and face masks to telehealth solutions to enable remote doctor consultations. A number of organisations across the MTP sector have been able to pivot their activities and resources to support these opportunities and needs that have arisen due to the pandemic.

Research institutions such as the CSIRO have redeployed significant staff, facilities and resources through their Health and Biosecurity unit and the Australian Centre for Disease Preparedness to focus on developing and testing potential vaccines against SARS-CoV-2. They have also focused efforts on advanced manufacturing of face masks and face shields, as well as providing federal and state health agencies with COVID-19 data tracking and forecasting to support decisions around Australia's outbreak response³⁰.



Responses



Pivoting resources to R&D for COVID-19 vaccines



Since February 2020 market capitalisation change...

CSL Limited 4% ASX: all Ords

24%

Mobilising R&D activities

CSL quickly mobilised and increased R&D activities related to the development of COVID-19 vaccines and therapeutics. This included developing a centralised COVID-19 team, drawing on multiple therapeutic areas and senior staff from around the global to collaborate with shared purposes, on one master protocol

"... We have become agnostic to the therapeutic areas and we very quickly created a COVID 19 team from multiple resources..."

— Dr. Charmaine Gittleson, Chief Medical Officer, CSL

Clinical trials on hold

CSL has put c.90% of its clinical trials on hold, globally. Within Australia, it has paused recruitment for all clinical trials in an effort to ensure patient safety and to free up hospital and resource capacity to support the COVID-19 response

Collaboration with Red Cross to produce COVID-19 Immunoglobulin

CSL has partnered to develop the hyperimmune Lifeblood and to assist in the collection of plasma in order to develop a potentially life-saving treatment for COVID-19 locally in Victoria. As a result, Australia will be one of the first in the world to commence development of a COVID-19 immunoglobulin

Redundancy already built into supply chain

CSL has seen no major impact to its supply chain or manufacturing, having already built in redundancy due to prior events leading them to run scenario modelling

³⁰ CSIRO, Coronavirus and infectious disease research, May 2020



CSL has pivoted its R&D efforts to begin development of an anti-SARS-CoV-2 plasma product with the potential to treat patients with serious complications of COVID-19 at its manufacturing facility in Victoria³¹. CSL is also actively developing collaborations with other biotech companies globally (e.g. SAB Biotherapeutics) to identify and develop potential immunotherapies to treat COVID-19 patients³². The case study below provides further detail on the various efforts CSL has taken in response to COVID-19.

In addition, organisations that have not traditionally been MTP sector participants, such as Detmold, and numerous local breweries and distilleries have pivoted their activities to help address the key gaps in products and services (e.g. face masks, hand sanitisers) that have arisen during the pandemic. The TGA has provided vital advisory support and regulatory flexibility to support these organisations to become suppliers of medical products and services within a rapid timeframe. Austrade has been supporting organisations requiring supply chain support in a number of ways, including the International Freight Assistance Mechanism (IFAM), as a temporary measure to help restore critical supply chains that have been heavily impacted by COVID-19³³. A network of 15 freight forwarders and air freight service providers has been established to support IFAM and ensure essential imports such as medicines and medical supplies can be transported to Australia.

MTP sector organisations that have been able to pivot their activities and efforts during the pandemic have been able to identify relevant needs and opportunities in the marketplace that align with their capabilities and expertise, act on regulatory guidance and flexibility that has been provided by the government agencies like the TGA and Australian Competition and Consumer Commission (ACCC) and be able to redeploy staff and resources to these needs rapidly.

Decline in activity without an opportunity to pivot

The third category of responses observed is by organisations who have suffered a significant decline in demand for their products / services and have not had an opportunity to pivot their activities during the pandemic. These organisations have taken actions to weather the consequences of the pandemic as much as possible and maintain financial and operational viability until the MTP sector, and the broader Australian economy, begin to recover. Most of these organisations are not able to pivot their activities and resources because the emerging areas of need are not aligned to the organisations' core competencies, and there are no obvious ways for them to redeploy their staff and / or resources effectively.

For example, early-stage pharma / biotech companies with non-COVID-19 related assets who are focusing on clinical trials and R&D have suffered from clinical trials being placed on hold during the pandemic. To compound matters, these companies have not been eligible for payroll relief through the JobKeeper scheme because they are pre-revenue and therefore ineligible for the scheme. The responses of these organisations have centred on surviving the pandemic with sufficient financial viability so that they can bounce back when the pandemic eases.

Medtech companies whose product portfolios are primarily geared towards elective surgery (e.g. Cochlear, Stryker), and universities and MRIs who are dependent on the flow of international students and researchers into their institutions are examples of organisations who have had to focus on survival through the pandemic. The case study below illustrates the responses taken by Cochlear to weather the negative impacts of the COVID-19 pandemic on the business.

³¹ CSL Behring, CSL Behring Australia commences development of treatment for serious cases of COVID-19, 6 May 2020

³² CSL Behring and SAB Biotherapeutics, CSL Behring and SAB Biotherapeutics join forces to delivery new potential COVID-19 therapeutic, 8 April 2020

³³ Austrade website, International Freight Assistance Mechanism, accessed on 1 June 2020





Case study: Cochlear Limited

The leading manufacturer in implantable hearing devices designed to assist people with moderate to profound hearing loss

Cochlear has experienced significant declines in sales and bookings due to restrictions on elective surgeries

Cochlear has implemented a number of reactive and protective responses, as well as a strategic response around R&D

Responses



Reduction of productive capacity

Due to restrictions on elective surgeries resulting in a sharp loss of demand for Cochlear devices, Cochlear has reduced its manufacturing output to manage inventory levels

From April Cochlear started temporarily reducing manufacturing output and staff working hours, including at its Australian sites

With adequate safety stock to meet expected fluctuations Cochlear determined it was not necessary to produce inventory or safety stock at the usual rate for some weeks. Cochlear has ensured it can quickly return to normal production output as demand increases

"... The need to reduce production hasn't been a result of social distancing measures but rather as a result of reducing supply to meet demand..."



Cash flow controls

As a result of the rapid loss of revenue experienced by Cochlear, it moved quickly to reduce its cost base wherever possible and increase its access to capital

These cash flow strategies included:

- \$1.1 bn capital raise
- Increasing debt facilities
- Accessing Government wage subsidies including JobKeeper
- Pay and hiring freeze

Cochlear are taking measures to prevent redundancies and minimise impact to salaries, one example is by establishing a global system for re-allocating resources internally where there is excess capacity

"... We have had a global program where people with less to do are who can work remotely are being reallocated to other parts of the business..."



Prioritisation of R&D

In order to best serve their customers in the long term, while also triaging costs, Cochlear has prioritised its R&D spend

As the market leader Cochlear is in a strong position to focus on its strengths and weather the impact better than some of its competitors

While there has been some reallocation of resources in projects including R&D, spending on digital and remote care has been accelerated. Cochlear has the technology to provide remote device checks and trouble shooting. It is ramping up its focus this area in order to enhance its delivery of care both during COVID19 and beyond

ensure when we emerge from this that our research pipeline is still in place so we will hit the ground running..."

— Senior Manager Cochlear

As the Cochlear case study illustrates, MTP sector organisations in this category have taken three common responses:

- reduction in operational activities and spending
- rationalisation of R&D and investment plans
- receipt of government support schemes

Reduction of activities and spending

To conserve cash and budget for the impact on their organisations, many took steps to reduce activities and spending. 37% of survey respondents reduced staff costs by reducing hours or number of employees. Deakin University recently announced its plans to make 400 positions (equivalent to 3% of



their total workforce) redundant, as it expects to lose between \$250 million to \$300 million next year³⁴. The Australian National University is considering a similar move as the pandemic has resulted in a \$225 million in blow to its budget³⁵. Some pharma and medtech companies who saw an immediate plummet in demand opted to reduce their operations and manufacturing capacity in Australia. Others reviewed costs, removed discretionary spend and delayed or stopped plans for larger spend projects, such as capital works and substantial maintenance plans. For example, AusBiotech based on a survey of their members in April cited an overwhelming response about the need to conserve cash, as smaller firms have not qualified for JobKeeper and require clinical trials to progress as soon as possible.

Rationalisation of R&D and investment plans

The shock of the pandemic has caused organisations to reflect on where they needed to prioritise their work. As outlined within the impacts in Chapter 2, 75% of those surveyed reported delays in investment plans. Organisations such as universities, research institutions and early-stage biotech / medtech companies have paused and assessed their priorities. One example of this is a venture capital firm who has been "very selective on deploying capital" while making decisions about what the future will look like³⁶. Additionally, Cochlear reprioritised its R&D spend by reducing spending on some projects and increasing spending on those projects that would allow it to better deliver care in the pandemic environment.

Receipt of government support schemes

Thirdly, organisations have sought support available through JobKeeper and a range of state government initiatives to bolster their financial positions. 70% of those surveyed indicated they utilised these schemes. While federal and state support mechanisms have been helpful, they have not been accessible to some organisations, such as early-stage MTP sector companies and research institutions (universities and MRIs). Consequently, these organisations will continue to face significant financial and operational pressure for many more months.

Minimally impacted by COVID-19 (negatively or positively)

Lastly, a handful of organisations have been minimally impacted by COVID-19 because the demand for their products / services has not been severely affected by the pandemic. Some service providers such as IP advisors and market access advisors are unlikely to have experienced a significant impact, as well as potentially some pharmaceutical companies who supply essential medicines, particularly where they can be supplied to consumers in their home or without the need for a medical procedure.

Consequently, these organisations have responded primarily to the constraints imposed by the COVID-19 restrictions (i.e. working from home, stricter hygiene / cleaning protocols, social distancing measures).

In summary, MTP sector organisations have taken a broad range of responses in dealing with the challenges posed by the COVID-19 pandemic. While some organisations have made the most of opportunities to support the pandemic response such as a surge in demand, or pivoted their activities to provide much needed solutions, others have struggled and are focusing on ensuring they survive the pandemic with the hope they will be in a position to rebound.

 $^{^{34}}$ Adam Carey, Deakin Uni to shed 300 jobs as tertiary sector's COVID-19 woes grow, The Age, 25 May 2020

³⁵ Fergus Hunter, ANU looks to cut staff as it tackles a \$225 million budget hole, Sydney Morning Herald, 27 May 2020

³⁶ Senior stakeholder interview with international venture capital firm based in Australia



4. The road to recovery & emerging lessons

As of 1 June 2020, Australia has begun the process of easing restrictions put in place to control the spread of COVID-19, using the three-step plan set out by the National Cabinet³⁷. The progressive easing of restrictions by states and territories is allowing for regional overnight travel, the opening of restaurants and cafes to limited patrons, schools reopening and much more. For the MTP sector, there are hopes that the announcement of \$400 million in federal funding for the discovery of new treatments for serious health conditions³⁸ and the gradual return to normal for other programs and for business will see a gradual restart of clinical trials and laboratory-based R&D activity.

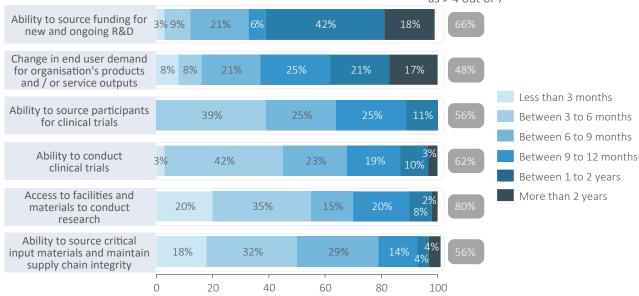
The majority of survey respondents (60%) indicated that impacts on clinical trials would continue for another six months or longer. Similarly, over half of respondents reported that implications on supply chain integrity and access to facilities and materials would last another six months or longer. The impacts on R&D funding and end-user demand for products / services are expected to last longer; between nine months to over a year.



Expected length of significant impacts, by respondents who ranked significance of impact to be greater than 4 out of a 7 point scale

Percent of respondents (N=50)

% of total respondents who ranked significance as > 4 out of 7



Question: Q8. As a result of the COVID-19 outbreak, how would you rate each of the following in terms of their impact on your business? (Please rate each these below on a scale of 1 to 7 where '1' means "very little impact" and '7' means "very significant impact); Q9. How long do you think the impact of COVID-19 will last for your organisation when considering each of those impacted areas? (i.e. until when the organisation is operating within 10-15% of normal activity levels before the COVID-19 outbreak)

Source: L.E.K. Pulse Survey 2020

The Hon Scott Morrison MP, Prime Minister of Australia, Update on Coronavirus measures – media statement, May 2020,

³⁸ Cassandra Bain and Nick Houghton, Hopes 400 million government health fund will boost coronavirus research restart clinical trials, SBS News, 20 May 2020

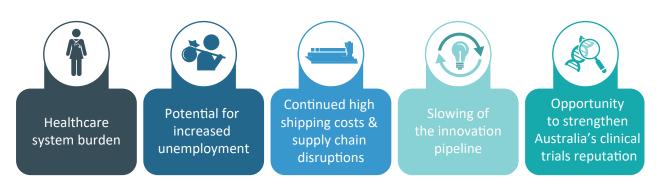


This chapter will discuss the impacts that are likely to affect the MTP sector in the short-medium term as the sector begins to recover from the COVID-19 pandemic. It will highlight areas where the sector is likely to require additional support as it recovers from the negative impacts of the pandemic, and present a preliminary view of some key lessons learned through the collective experiences of the sector over the past four months that could help mitigate against the impacts of future such pandemics.

The road to recovery for the MTP sector

The road to recovery for the MTP sector is likely to be a difficult one with many uncertainties. It is currently unclear whether there will be subsequent waves of heightened community transmission of COVID-19 requiring further shutdowns. It is unclear how long Australians will need to socially distance and how cautious they will be at returning to previous behaviours, including receiving medical treatment. There is uncertainty around ongoing international border closures and movement of goods and it is also unclear how the broader Australian economy will be affected and how reduced consumer wealth and funding sources will impact on demand for MTP products and services. The MTP sector will need to continue to be agile.

There are five key factors across the MTP value chain that will affect the sector over the next six to twelve months, as summarised below.



In order to mitigate against these five key factors, a number of actions will need to be taken as part of rebuilding strategies to ensure the MTP sector recovers effectively from the crisis and can continue its significant contribution to economic and jobs growth and improving the health and wellbeing of Australian and international consumers.



Implications

Medicare Benefits Schedule (MBS) data for April shows that the pandemic has led to a 20% reduction in GP visits, 50% fewer specialists' appointments and a 40% drop in pathology tests when compared to April 2019³⁹. In combination with clinical trials being put on hold, this implies that delays with patient diagnoses and treatments are building within the broader community during the period of this pandemic.

³⁹ Yajun Ma, Doc visits crash as virtual soars, Pharma in Focus, 27 May 2020



Once COVID-19 restrictions are lifted, the healthcare system is likely to be challenged by not only a surge in the volume of patient consultations but also an increase in the severity of interventions (treatments, surgeries) as patients are likely to have more progressed disease symptoms.

Path to recovery

A consortium of healthcare stakeholders has joined forces through the 'Continuity of Care Collaboration' to mitigate against this scenario by stressing the importance of people continuing to monitor their health, seeking support for chronic issues and maintaining regular medical care⁴⁰. The collaboration commenced in early May 2020. It is crucial for the sector that public and private sector organisations and government continue to work together to encourage patients to seek regular medical care.



Potential for increased unemployment

Implications

The Australian Government's JobKeeper scheme has supported a wide range of businesses across the economy in maintaining staffing levels during the COVID-19 pandemic. As the JobKeeper scheme is wound back over the coming months, there may be an increase in unemployment across the economy, particularly if JobKeeper support is scaled down before a sufficiently strong recovery in market conditions. Job cuts are likely to increase at organisations which have not qualified for JobKeeper support, including early-stage MTP companies who are pre-revenue and research institutions. For example, the research sector, comprising researchers in universities, government, non-for-profits and industry sector, expects 20,000 jobs to be lost over the next 12-14 months due to the re-sizing of universities and reduction in funding from philanthropic and commercial sources. This impact will be further amplified as the loss of international student revenue will last for at least three years⁴¹.

Path to recovery

Pre-revenue and early-stage biotech and medtech companies are seeking support to expand JobKeeper eligibility criteria to include some 68,000 highly skilled employees⁴² who work in the sector. These are some of the same individuals responding to COVID-19 by conducting essential research, developing vaccines, supporting diagnostics and developing digital solutions. An alternative policy approach is for government to support these pre-revenue and early stage companies by matching capital through several mechanisms, including revenue contingent, convertible loans. Sustaining foreign investment in the Australian MTP sector is critical and can be achieved through continued R&D tax incentives and a comprehensive plan to ensure all aspects of the value chain are incentivised. Stakeholders have warned that the loss of access to capital for early-stage, innovative organisations in the sector could lead to a generational loss of start-ups and their IP.

⁴⁰ Natalie Wimmer, Medicines Australia joins forces with 15 healthcare organisations to highlight continuity of care, Medicines Australia, 6 May 2020

⁴¹ Alan Finkel, Rapid Research Information Forum: COVID-19 Research Workforce, Australian Academy of Science, 6 May 2020,

⁴² PulseLine, Industry unites to back jobs during COVID-19, Medium, 22 May 2020





"... the nation could face "generational loss" of biotechs and medtechs that are not eligible for the JobKeeper subsidy since it does not support pre-revenue innovation companies..."

Chris Nave, Founding Partner and Managing Director, Brandon Capital Partners⁴³



Continued high shipping costs and supply chain disruptions

Implications

While international travel is restricted, reduced capacity for international air freight and the resulting higher freight costs will continue to affect Australian businesses who are already managing challenging operating environments. As long as this continues, companies will face compounding financial pressures due to lower revenues and lower margins.



"For some of the lower value products such as PPE, and some multi-brand and over-the-counter medicines, it got to the point where air freight costs exceeded the cost of goods"

- Elizabeth De Somer, CEO, Medicines Australia

Path to recovery

There is a need to continue growing capacity of air freight and improve its cost effectiveness in order to support MTP sector organisations that are reliant on the ability to cost effectively import and export goods to and from Australia. Government departments and agencies such as DISER, through the COVID-19 Industry Taskforce working groups and Austrade have moved swiftly and decisively in assisting MTP sector organisations secure critical air freight capacity over the past three months. This support needs to be continued and expanded to ensure cost effectiveness of air freight services in order to better aid the recovery of MTP sector organisations who are reliant on the ability to import and export goods to and from Australia.



Slowing of the innovation pipeline

Implications

Basic research activity drives the early stage pipeline of innovations in the MTP sector. Research institutions such as universities and MRIs are under significant financial pressure when it comes to covering the costs of their research activities, as we have outlined in Chapter 2.

⁴³ Carrie LaFrenz, Biotechs face 'generational loss' without JobKeeper, Australian Financial Review, 25 May 2020





"The University of Sydney needs to find \$1.52 of revenue to cross-subsidise every \$1 of government research funding we receive."

— Duncan Ivison, DVC (Research) The University of Sydney & Chair, Group of Eight

While this shortfall in research funding has existed prior to COVID-19, the pandemic has exacerbated the issues because of the lack of alternative revenues to cover this shortfall. Consequently, research institutions could be required to rationalise their research efforts to maintain their financial sustainability. This will significantly impair the volume and diversity of discoveries and inventions coming out of these institutions, eventually resulting in lower commercialisation outcomes and innovative output across the MTP sector. Consequently, it is likely that the pipeline of new innovations – therapeutics, medical devices and services – will slow over the next six to twelve months.

Path to recovery

In order to maintain and grow Australia's global reputation for basic medical research and innovation, sector stakeholders have voiced a need to review the research funding model in Australia. Such a review can also help shape the country's innovation agenda for the future and address concerns on the budgetary pressures facing the country as it recovers from the pandemic.

Collaborative efforts by governments and research institutions are also required to safely expedite international students returning / coming to Australia for their education once travel bans are lifted. A resurgence of international student flows, particularly from China, will be critical to ensuring long-term research sustainability. Rising geopolitical tension with China, Australia's largest international student market, has been flagged as an emerging area of concern which may impact future enrolments.



Opportunity to strengthen Australia's clinical trials reputation

Implications

Whilst strengthening Australia's clinical trials reputation is a longer-term strategic priority, there is a short-term opportunity to leverage Australia's position as one of the lesser affected Organisation for Economic Co-operation and Development (OECD) nations. International organisations could view Australia's robust health and medical research infrastructure, skilled workforce and stability as an opportunity to relocate parts of their business to conduct clinical trials and other related R&D activities.



"Australia's successful management of the COVID-19 pandemic and reopening of our economy brings real opportunities to attract greater numbers of clinical trials here that would otherwise be done in the US, Spain, Italy and Germany or other countries severely affected by COVID-19. It highlights the unique position Australia is in to capture new business, build the sector further and enable our public health system to respond to the needs of patients with life-threatening conditions. We have the opportunity to remain world-leading in our pursuit of clinical trials allowing Australian patients to have early access to innovative medicines, therapies and vaccines sooner."

- Elizabeth De Somer, CEO, Medicines Australia



Path to recovery

In order for clinical trials to ramp-up as the pandemic restrictions ease, it is critical that the sector collectively develops the following:

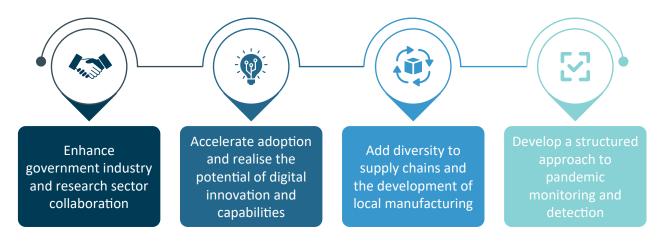
- Strategies increasing patient recruitment for clinical trials and restarting trials that were put on hold during the pandemic, including risk mitigation plans to cope with further waves of infection which may arise over the next six months
- Embed regulatory processes and mechanisms that have enabled greater responsiveness and flexibility in conducting clinical trials (e.g. approval for variations, ethics committees)
- Enhance market awareness of Australia as a destination where clinical trials are quickly returning to normal

Longer term concerns

The presence of a strong pharmaceutical and medtech sector with in-market products plays a vital role in ensuring cross-pollination of skills and capabilities into Australian research and biotech companies to support successful translation and commercialisation of Australian innovation. Many in the sector are concerned about the longer term impact of COVID-19 on the government budget position and whether this will translate into reductions in funding and savings measures from the sector into the future. R&D tax incentives were adjusted for FY2020 and organisations have expressed concern that reimbursement for pharmaceuticals and devices through the MBS, PBS and prostheses list will be affected without HTA justification as a means to reduce the budget deficit.

Emerging views on lessons learned from the pandemic

Although the impacts of the COVID-19 pandemic on the MTP sector are yet to be fully realised, our engagements with senior MTP sector stakeholders have highlighted a few key lessons learned from the journey thus far in dealing with the pandemic. The four key lessons learned so far, illustrated in the figure below, will help the sector better mitigate against the impacts of future such pandemics.





Enhance government industry and research sector collaboration

Significant work has been undertaken to align efforts across states and territories in Australia, especially with R&D and procurement for COVID-19 preparedness. This collaboration and lowering of state barriers has been regarded as a quantum leap forward and has been anecdotally mentioned as the most significant change from COVID-19 that should remain, to continue to drive changes.



"...Our mindset needs to change from where we were to where we are now. There needs to be more empathy and understanding of what each group is working towards because we can be far more effective when working together with a collaborative mindset. We should move forward with this regardless of future pandemics or not..."

James Doyle, Lead, MTAA Ventilator Workstream & Senior Director –
 Commercial & Public Affairs, Stryker

The industry / government collaboration has demonstrated that Australia's medical technology sector is uniquely placed to inform and deliver sovereign manufacturing capabilities and robust supply chains as part of future pandemic planning.

The collaboration has highlighted the criticality of the need to be able to rapidly access good data across supply chains to understand the quantities and location of PPE and medical supplies within states and territories and in the case of medicines, at a local level. In addition, taking action early to bring together a cross-functional group to problem solve has been observed as a great lesson learned.

Accelerate adoption and realise the potential of digital innovation and capabilities

With the large shift to remote working and the widespread uptake of telehealth consultations, learnings have emerged on key technologies and digital capabilities that will be needed to continue this shift. In April, in the peak of the COVID-19 wave, there were 20% fewer GP visits and 43% fewer visits to specialists compared to the same month in 2019. Additionally, virtual consultations have grown exponentially, with five times more in April than in March⁴⁴ with over 4.2m telehealth consultations delivered in the six weeks up to 20 April 2020⁴⁵. Remote access to data for clinical trial teams, the introduction of remote / at-home monitoring of patients, the introduction of a COVID-19 tracking app, and the ability to e-sign documents are examples of broader digital health capabilities within Australia that have been successfully adopted in Australia during COVID-19. An on-going accelerated rate of adoption of digital health innovation will be critical to drive productivity gains and improve the quality of healthcare deliver in Australia. Fit-for-purpose regulatory frameworks such as well-defined telehealth reimbursement codes will need to be developed rapidly and further iterated to support these innovations and support rapid uptake of such value-added services.

Add diversity to supply chains and the development of local manufacturing

The success of the notus Consortium rapidly manufacturing 2,000 ventilators by leveraging domestic manufacturing capabilities has demonstrated the power of advanced Australian manufacturing⁴⁶.

⁴⁴ Yajun Ma, Doc visits crash as virtual soars, Pharma in Focus, 27 May 2020

The Hon Greg Hunt, Australians embrace telehealth to save lives during COVID-19, 20 April 2020

⁴⁶ MTPConnect and MTAA, Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19, June 2020



<u>Case study</u>: National ventilator response

Key collaborators to addressing the rapid demand for ventilators in Australia













The mapping and modelling of Australia's footprint and supply of essential ventilator units. This included the production of over 6,000 ventilators by Australian parties, as well as the securing of global componentry and parts

Responses and lessons learned



Collaboration is essential

The collaboration of industry leaders, associations and government was key in driving the success of this project

It demonstrates what can be achieved when stakeholders work together. Within two weeks, the ACCC approved cross collaboration of organisations and associations and all of Australia's ventilator manufacturers met to understand supply

Once manufacturing begun, The Department of Industry and Department of Health assisted with transport of materials and essential worker permission respectively

While the Federal response was procurement-led stimulus, as highlighted in the MTPConnect / MTAA Ministerial Briefing Paper, the collaboration was driven by the medical technology industry. Institutional coordination mechanisms were invented under immense time pressure including the AMGC's COVID-19 Manufacturer response register designed across multiple stakeholder groups

Future pandemic plans should learn from the experience of mobilising health technology early to aid response

"... to get companies to come together in that environment and have open discussions around their supply chains and input costs to help the country was quite inspiring to be a part of..."

— Ian Burgess, CEO, MTAA



Regulatory pathway • exemptions

In order to quickly move to production and importation of ventilators, the TGA was required to quickly approve new ventilator designs In a two-week period, the TGA approved between 7 and 9 ventilator designs for manufacture and use in Australia In addition to rapid approvals, the TGA took on a heavy workload around providing non-regulatory advice and guidance to industry, with over 2,200 new manufacturers entering the market from February to April. Similarly, the TGA were able to approve a US ventilator design that had not been approved by the FDA, providing Australia with access ahead of existing US orders

In the COVID-19 pandemic, the role of the regulator has emerged as critical and is a key learning for future planning. Industry collaboration with the TGA not only allowed for rapid approvals, but also assisted with the identification of unscrupulous players and well-intentioned amateurs to keep sub-standard equipment from entering the market

"... This was extremely collaborative and trusting of these companies, it was also exceptionally fast to form strong relationships..."

— James Doyle, Lead, MTAA Ventilator Workstream & Sr. Director, Stryker



Proving Australian capability

Grey Innovation has led manufacture of ventilators in the Australian response effort through the notus Vivere Emergency Invasive Ventilator Program with support from the Commonwealth and Victorian governments and AMGC. With the government enacting this procurement-led stimulus, Grey increased work and directly employed an additional 22 people, with close to 300 jobs retained or generated across the consortium, in order to produce 2.000 ventilators

The ventilator taskforce introduced three local companies to provide ventilator circuitry, one of which was able to repurpose 86 staff who otherwise would have otherwise been furloughed

Additionally, ResMed have tripled their production of ventilators, delivering 4,000 for the national stockpile

Current capabilities in Australia could help to develop a specialised sovereign manufacturing capability with a detailed understanding of Australia's capacity to design, produce, and service all components required for high demand medical equipment.

As part of a future pandemic plan, it may be possible for Australia to play a key role in a coordinated international supply chain initiative

"... The outcomes of this project will show that Australia can make things. We can and should be supplying critical materials..."

 Mandie Lammens, Group Operations Manager, Grey Innovation



Over 75% of stakeholders consulted cited that higher capacity and flexibility in local manufacture would better prepare Australia for future pandemics; some suggested that Australia could go one step further to prioritise local manufacturing by using mechanisms, such as incentives or tender requirements for a minimum portion of Australian made products. Other learnings shared were around ensuring a diverse supply chain and sources, with some organisations intentionally building in redundancies prior to COVID-19 which meant limited interruptions to supply these past 3 months. If Australia is to avoid shortages in medicines in a future pandemic, one option would be to incentivise companies to increase the levels of supply they hold in Australia or to increase national and state stockpiles.



"We may need to consider whether incentivising companies to keep more than 3-6 months' supply in the country at any given time is required; we should review options for stronger supply guarantees through international trade relationships, and reconsider incentives to retain the local manufacturing we currently have, and build on that in order to strengthen our supply chain and ensure patients continue to have access to medicines when they need them.

- Elizabeth De Somer, CEO, Medicines Australia

Develop a structured approach to pandemic monitoring and detection

The impact of COVID-19 on Australia has demonstrated the need to develop a more structured approach so that responses to future pandemics can be even more efficient and timely. The discussion with CSIRO shared insights on what is required to better prepare for future pandemics.



"There are four key stages for pandemic management and preparedness. They are predict and prevent, detect, respond and lastly, recover...progress can be made in the first two pillars through the facilitation and coordination of research and projects across the sector,"

— Rob Grenfell, Health Director, Health & Biosecurity, CSIRO

Many Australian researchers, start-ups and SMEs in the MTP sector are currently working in vaccine design and manufacture, diagnostics and imaging, bioprocessing technologies, ventilation technology, telemedicine, infection control and protection and immune system directed therapies. Stakeholder sentiment aligns with the focus on preparation and detection with over 60% surveyed suggesting there should be increased and more consistent and sustainable funding for research, development and manufacturing capabilities for infectious diseases and associated medical diagnostics, as it would better prepare Australia for future pandemics⁴⁷.

⁴⁷ Sophie McNeill, Jeanavive McGregor and Lauren Day, How Australia's 'panic and neglect' funding cycle has left us vulnerable to pandemics like coronavirus, ABC News, 8 June 2020



Conclusion

The COVID-19 pandemic, and the restrictions implemented to control its spread, have caused significant negative impacts to the MTP sector over the past three months. Commercial activity across the sector, as measured by the market capitalisation of ASX-listed MTP companies, has taken an \$11 billion (5%) hit and many sector companies and organisations have seen severe declines in revenue and margins. Supply chain integrity for many companies has been compromised and with a necessary emphasis on preserving cash until better times, jobs have been lost. Up to 90% of clinical trials have been put on hold and R&D activities have been slowed down or stopped. Complications in access to capital for early-stage companies could lead to a generational loss of start-ups from the Australian ecosystem.

And the sector has been battling these impacts while simultaneously working on the front line of the COVID-19 response, mustering resources to fast-track development of new vaccines, diagnostics, devices and therapeutics.

The MTP sector is innovative and resilient, characteristics which came to the fore in the unique collaboration between industry and government to ensure effective supply of the critical healthcare technologies, goods and services necessary to support the public health response to COVID-19. Many organisations have pivoted their own activities to contribute to the pandemic response, often absorbing higher costs and consequently lower margins. This has now placed Australia among the leading countries globally in terms of recovery from the pandemic.

The uncertain path over the next 6-12 months, with the possibility of future waves of infection, will have flow-on impacts for the MTP sector and the broader Australian economy. Sector leaders point to tens of thousands of jobs in universities, research institutes and early stage MTP companies being at risk. And there are concerns that efforts to plug substantial revenue shortfalls at universities will lead to a rationalisation of research activities and damage to the commercialisation pipeline. Prolonged declines in the number of general practice and specialist visits risks a growing population of undiagnosed patients and / or worsening health conditions among patients, which will in turn put additional pressure on the healthcare system; from access to hospital beds to supply of medical devices and medicines.

After a number of years of strong growth and sustained contributions to the Australian economy, COVID-19 is testing the MTP sector like never before. The insights in this report provided by senior leaders from across the MTP sector not only demonstrate the key role it is playing in responding to COVID-19, but also its importance to the recovery efforts and building sovereign capabilities for future pandemic resilience.

As the impact of COVID-19 continues to evolve, MTPConnect will continue to monitor the health and responses of the MTP sector. A follow-up report will be published in Quarter 3 2020 that will articulate a more comprehensive view on the lessons learned from the sector's collective experiences of the COVID-19 pandemic, outline strategies and initiatives to position it for future growth and enhance Australia's future pandemic preparedness.



Appendices

Appendix 1: Glossary of terms

AAMRI	Association of Australian Medical Research Institutes	IFAM	International Freight Assistance Mechanism
ACCC	Australian Competition and Consumer Commission	IMF	International Monetary Fund
AFR	Australian Financial Review	IP	Intellectual Property
AMGC	Advanced Manufacturing Growth Centre	MA	Medicines Australia
API	Australian Pharmaceutical Industries	MBS	Medicare Benefits Schedule
ARC	Australian Research Council	MRFF	Medical Research Future Fund
ASX	Australian Securities Exchange	MRI	Medical Research Institute
CEPI	Coalition for Epidemic Preparedness Innovation	MTAA	Medical Technology Association of Australia
CEO	Chief Executive Officer	MTP	Medical technology, biotechnology and pharmaceutical
COO	Chief Operating Officer	NHMRC	National Health and Medical Research Council
CPAP	Continuous Positive Airway Pressure	OECD	Organisation for Economic Co-operation and Development
CRO	Contract Research Organisation	PBS	Pharmaceutical Benefits Scheme
CSL	Commonwealth Serum Laboratories	PPE	Personal Protective Equipment
CSIRO	Commonwealth Scientific and Industrial Research Organisation	PTA	Pathology Technology Australia
DFAT	Department of Foreign Affairs and Trade	R&D	Research and Development
DISER	Department of Industry, Science, Energy and Resources	SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
DoH	Department of Health	SCP	Sector Competitiveness Plan
FY	Financial Year	SME	Small to Mid-sized Enterprise
GDP	Gross Domestic Product	TGA	Therapeutic Goods Administration



Appendix 2: Details of Australian government support packages

There have been a number of support packages and measures introduced by the Federal and State Governments to support businesses through the COVID-19 pandemic. These support measures are as at 1 June 2020, refer to Federal and State websites for up to date information.

Federal measures

Aid package ⁴⁸	Description	Eligibility	
JobKeeper	Payment made to eligible businesses affected by COVID-19 to support them in retaining employees	If business turnover < \$1b must demonstrate that turnover is likely to have reduced by 30% in the relevant month or three months when	
	Eligible businesses will receive \$1,500 per fortnight per eligible employee	compared to the previous year If turnover > \$1 billion must demonstrate a reduction greater than 50%	
	Available from 30/03/20 – 27/09/20		
Instant asset write-	Accelerated depreciation for 15 month	Applies from 12/03/20 to 30/06/20	
off and accelerated depreciation	investment incentive to support business investment. Immediate deduction of 50% of the cost of an eligible asset on installation will apply, with existing rules applying to the balance of the cost	Business aggregated turnover < \$500m	
	Instant asset write off has increased threshold from \$30 thousand to \$150 thousand	Authorized assets that can be depreciated under Income Tax Assessment Act	
Other ATO COVID-19 relief measures	 Deferral of payments PAYG Instalments GST Reporting Remitting interest / penalties 	Varied	
Cash flow assistance for SMEs	SMEs that employ workers may receive a tax- free payment of between \$20 thousand and \$100 thousand	Businesses aggregated annual turnover < \$50m	
Support the flow of credit	'Coronavirus SME Guarantee Scheme' where the Government will provide a 50% guarantee on new loans made by SMEs for working capital purposes	Businesses aggregate annual turnover up to \$50m	

⁴⁸ Source: Ausbiotech and Deloitte, COVID-19 cash back opportunities and tax stimulus packages, Biotech Talks Ausbiotech webcasts



State and Territory measures

Packages by location ⁴⁹	Description	Eligibility
Queensland	Payroll tax refund / tax holiday / deferral	By application
	Rent relief	By application
	Grants	By application
New South Wales	Payroll tax reduced / defer	Dependent on payroll spend
	Land tax concessions and relief	Varied
	Small business support grants	By application
	Tax deferral exemptions	By criteria
Victoria	Payroll tax waiver / deferral	Dependent on payroll spend
	Land tax deferral	By criteria
	Grants	By application
Western Australia	Payroll tax waiver / threshold	Dependent on payroll spend
	One-off grant	Automatic for \$1-4m payroll
	Tax deferral interest / fee free	Automatic
	Other measures such as, waiving rent, cashflow for tourism companies	Varied
South Australia	Payroll tax waiver / deferral	Dependent on payroll spend
	Land tax deferral	By criteria
	Emergency grants	By application
	Other measures such as new hire funding, waiving fees	Varied
Tasmania	Payroll tax waived / refunded	By application / industry
	Land tax waived	By criteria
	Small grants for apprentices	Certain industries
Australia Capital Territory	Payroll tax waiver / deferral	By criteria
	Land tax relief	By application
	Other measures such as commercial property rebate and fee waivers	Varied
Northern Territory	Central Hardship Register (CHR)	By application
	Payroll tax waiver / deferral	By criteria
	Lowered utilities by 50%	Registered for CHR
	Other measures such as Business Survival Fund, fee freezing	Varied

⁴⁹ Source: Ausbiotech and Deloitte, COVID-19 cash back opportunities and tax stimulus packages, Biotech Talks Ausbiotech webcasts



Appendix 3: Detailed methodology of research

The material contained in this report was developed using three main research tools – an online pulse survey targeted C-suite executives at MTP sector organisations, targeted stakeholder interviews with MTP sector leaders, and desktop research. Further details are outlined below. In total, this report was developed based on the perspectives of over 80 senior executives across various MTP sector organisations.

Methodology

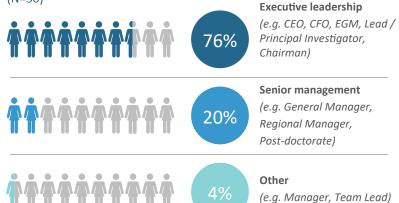


Pulse survey: A brief 10 minute pulse survey was sent to a focused group of C-suite executives from

all segments and areas of the MTP value chain. The figure below shows the distribution of pulse survey respondents by organisation type and their level of seniority within their respective organisations. The survey asked questions relating to the impacts sustained from COVID-19 and their severity, as well as how the organisation had responded, where they required additional support and

Survey response distribution, by respondent seniority

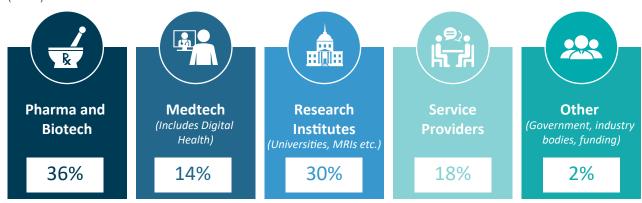
Percent of overall respondents (N=50)



what preliminary lessons they had learned through their experiences of COVID-19.

Survey response distribution, by sub-sector

Percent of overall respondents (N=50)



Question: Q1. What type of organisation do you work for?

Source: L.E.K. Pulse Survey 2020





Stakeholder interviews: L.E.K. and MTPConnect conducted in-depth interviews with 26 key industry stakeholders to better understand the impacts on their organisations due to COVID-19, their responses to the crisis and lessons learned from the experience thus far. Discussions with industry organisations / membership bodies also involved understanding the impacts and responses of relevant groups and sub-sectors.



Desktop research: A broad range of sources including industry journals, media outlets and periodicals were used to document the impacts of COVID-19 on different parts of the MTP sector. Analysis of specific metrics such as ASX market capitalisations was also conducted by L.E.K. Consulting on behalf of MTPConnect.



Appendix 4: References

Author(s), Organisation	Title	Month (2020)
Addinor(s), Organisation Adam Carey, The Age		
Australian Manufacturing Forum	Deakin Uni to shed 300 jobs as tertiary sector's COVID-19 woes grow On The Defense Production Act and ResMed	May April
Carrie LaFrenz, Australian Financial Review	ResMed ready for COVID-19 waves after ramping up ventilators	May
Carrie LaFrenz, Australian Financial Review	Biotechs face 'generational loss' without JobKeeper	May
Cassandra Bain and Nick Houghton, SBS News	Hopes 400 million government health fund will boost coronavirus research restart clinical trials	May
CSL Behring	CSL Behring Australia commences development of treatment for serious cases of COVID-19	May
CSL Behring and SAB Biotherapeutics	CSL Behring and SAB Biotherapeutics join forces to delivery new potential COVID-19 therapeutic	April
Damien Angus, Maureen Connolly and Mariella Salita, PwC	The shift to virtual care in response to COVID-19	April
Dr. Alan Finkel, Rapid Research Information Forum	COVID-19 Research Workforce	May
Emma Koehn, Sydney Morning Herald	Pharmacy players primed for drug home delivery booster shot	May
Frank Larkins, Australian Government Chief Scientist	Impact of the pandemic on Australia's research workforce	May
Global Data	Coronavirus (COVID-19) Executive briefing	April
Hien Lau and Veria Kohsrawipour, Science Direct	Internationally lost COVID-19 cases	March
GlobeNewswire	Resignation of CEO & Director and cost cutting amidst COVID-19	March
International Monetary Fund	Unemployment rate: advanced economies and Australia	April
International Monetary Fund	World Economic Outlook April 2020: The Great Lockdown	April
Jordan Baker, Sydney Morning Herald	Sydney University expects a \$470m loss due to coronavirus crisis	April
Maarten Ijzerman and Jon Emery, Pursuit University of Melbourne	Is delayed cancer diagnosis a consequence of COVID-19?	April
Matthew Cranston, Australian Financial Review	Treasury sees a faster economic recovery	June
MTPConnect	Sector Competitiveness Plan April 2020	April
MTPConnect, with MTAA	Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19	June
Natalie Wimmer, Medicines Australia	Medicines Australia joins forces with 15 healthcare organisations to highlight continuity of care	May
NHMRC	Update – Changes to NHMRC 2020 funding schemes <u>Website</u>	March



Author(s), Organisation	Title	Month (2020)
Paul Sakkal, The Age	All go at hand sanitizer factory amid a crisis 'bigger than Ben-Hur'	February
PulseLine	Industry unites to back jobs during COVID-19	May
Rachel Williamson, Stockhead	Investors can't get enough of telehealth as global funding surges in Q3	April
Rachel Williamson, Stockhead	Call the midwife: Telehealth has arrived	March
Senator the Hon Linda Reynolds CDC and the Hon Karen Andrews MP	Increasing domestic manufacturing during COVID-19	March
Sophie McNeill, Jeanavive McGregor and Lauren Day, ABC News	How Australia's 'panic and neglect' funding cycle has left us vulnerable to pandemics like coronavirus	June
Statista, Johns Hopkins University	Coronavirus (COVID-19) deaths worldwide per one million population	May
Stephanie Segal and Dylan Gerstel, Centre for Strategic & International Studies	Breaking down the G20 Covid-19 Fiscal Response	April
Stuart Elliot, on ABC Radio	Planet Innovation speaks about manufacturing supply chain resilience	April
The Hon Greg Hunt	Australians embrace telehealth to save lives during COVID-19	April
The Hon Scott Morrison MP, Prime Minister of Australia	Update on Coronavirus measures – media statement	May
Tom McIlroy, Australian Financial Review	'Tiger team' ready to export ventilators to aid COVID-19 fight	May
Thomson Reuters Datastream	ASX share price data	Jun-19 to Jun-20
The Treasury of the Australian Government	Economic Response to Coronavirus	April
Yajun Ma, Pharma in Focus	Doc visits crash as virtual soars	May



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