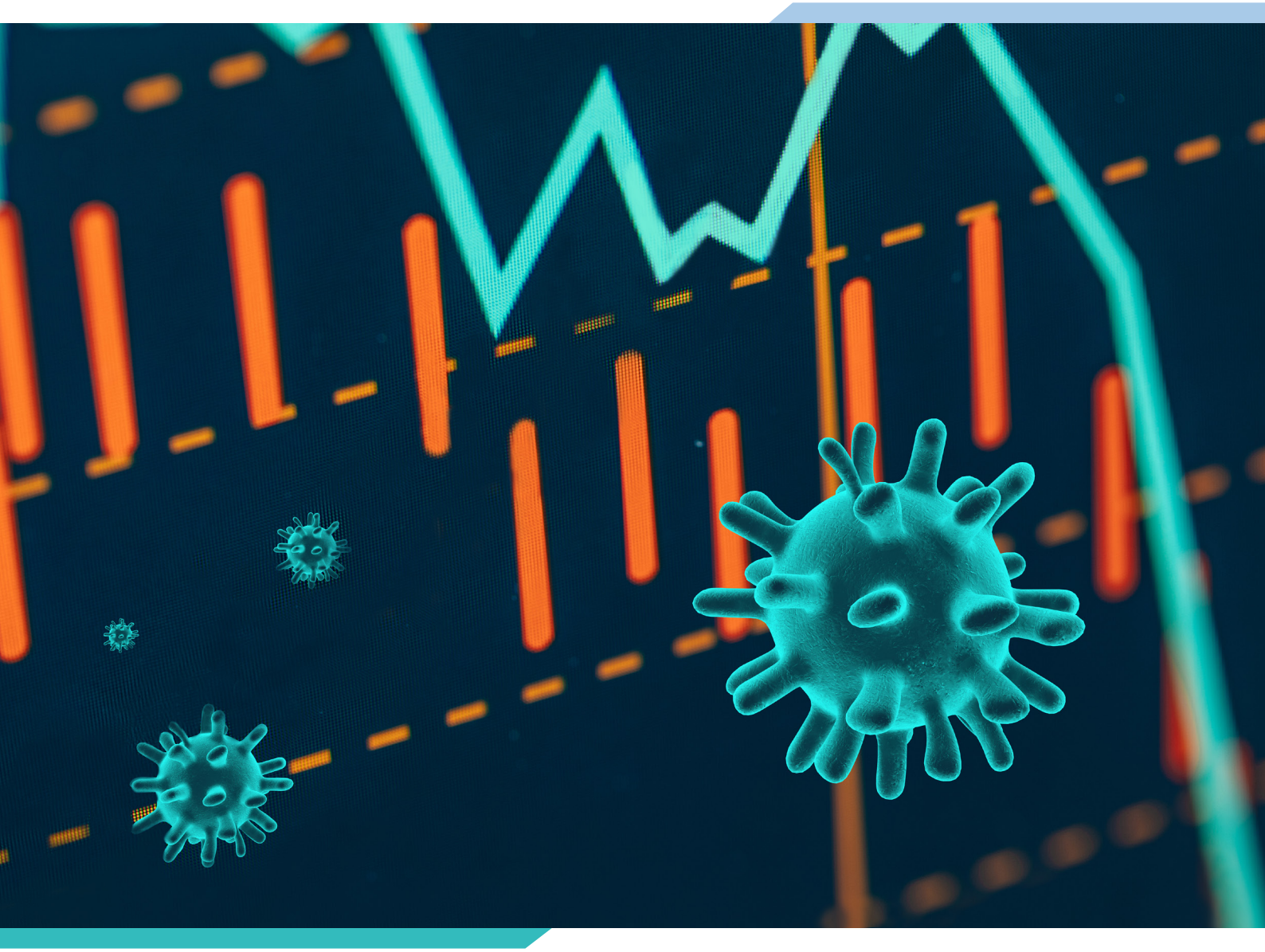
MTPConnect
MedTech and Pharma Growth Centre



# Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19

## Supplementary report to the MTPConnect COVID-19 Impact report

June 2020

Produced in association with

MTAA Medical Technology Association of Australia

# Contents

# 1. Introduction

With Australia confirming its first case of the coronavirus on 25 January 2020, it wasn't long before COVID-19, the disease caused by SARS-CoV-2, emerged as an international public health emergency which was classified by the World Health Organization as a pandemic on 11 March 2020.

As the number of cases continued to rise in Australia, and international border lockdowns increasingly contributed to trade, freight and supply chain restrictions, the Australian Government took action to stop the spread of the virus and prepare a medical response, including establishing the Health Industry Coordination Group (HICG). Chaired by Glenys Beauchamp PSM, former Secretary of the Department of Health and the Department of Industry, Innovation and Science, the HICG's Taskforce initiative brought together government agencies and private sector organisations to ensure effective supply of the critical healthcare technologies, goods and services necessary to support the public health response to COVID-19. MTPConnect, the Growth Centre for the medical technology, biotechnology and pharmaceutical sector, was involved with the Taskforce initiative from inception, through Chair Sue MacLeman.

In mid-March 2020, the Medical Technology Association of Australia (MTAA), under the leadership of Chair Maurice Ben-Mayor and CEO Ian Burgess, developed the framework for a COVID-19 Industry Working Group, involving MTAA member and non-member companies, to support the Taskforce and assist in securing essential supplies of ventilators, test kits, Personal Protective Equipment (PPE) and other ICU supplies required by the healthcare system to manage the pandemic.

MTAA is the major national association representing companies in the medical technology industry, including manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability.

The Working Group consisted of four substreams, bringing together medical device companies – large and small, MTAA members and non-members, domestic and multinational – who were able to form a cohesive, collaborative partnership with Federal Government agencies, including the Therapeutic Goods Administration (TGA). Teams of senior officials from the Department of Industry, Science, Energy and Resources (DISER) and the Department of Health were integrally involved in all Taskforce and Working Group activities, while from industry, James Doyle, Jeff Fryer, Daniel Kildea, Paul Davies and Mark Taffa, who have all chaired working streams, have made significant contributions. The Advanced Manufacturing Growth Centre (AMGC) also played a key coordination and collaboration role.

The Australian industry collaboration strategy is increasingly being recognised as one of the best responses globally, with the UK, Singapore and Japan now taking steps to replicate the taskforce / working group model. At an enterprise level, we are seeing the contribution of Australian operations of multinational firms being acknowledged by global leadership. Information about the Australian response is also being shared in international industry and science fora which is promoting Australian expertise and industry capability around the world.

For future pandemic preparedness planning, now is the opportunity to utilise the experiences and outcomes of this unique collaboration forged to tackle COVID-19, including lessons from SARS and earlier pandemics and understanding what worked well and what could be improved.

While the Taskforce initiative was concluded on Friday 22 May 2020, the collaboration with industry that it nurtured has profoundly impacted Australia's ability to deal with the COVID-19 crisis. This paper outlines the efforts and outcomes of this collaboration in support of the national interest and provides recommendations for future pandemic planning and the role of the medical technology industry.

## 2. Setting up the framework – Working Groups

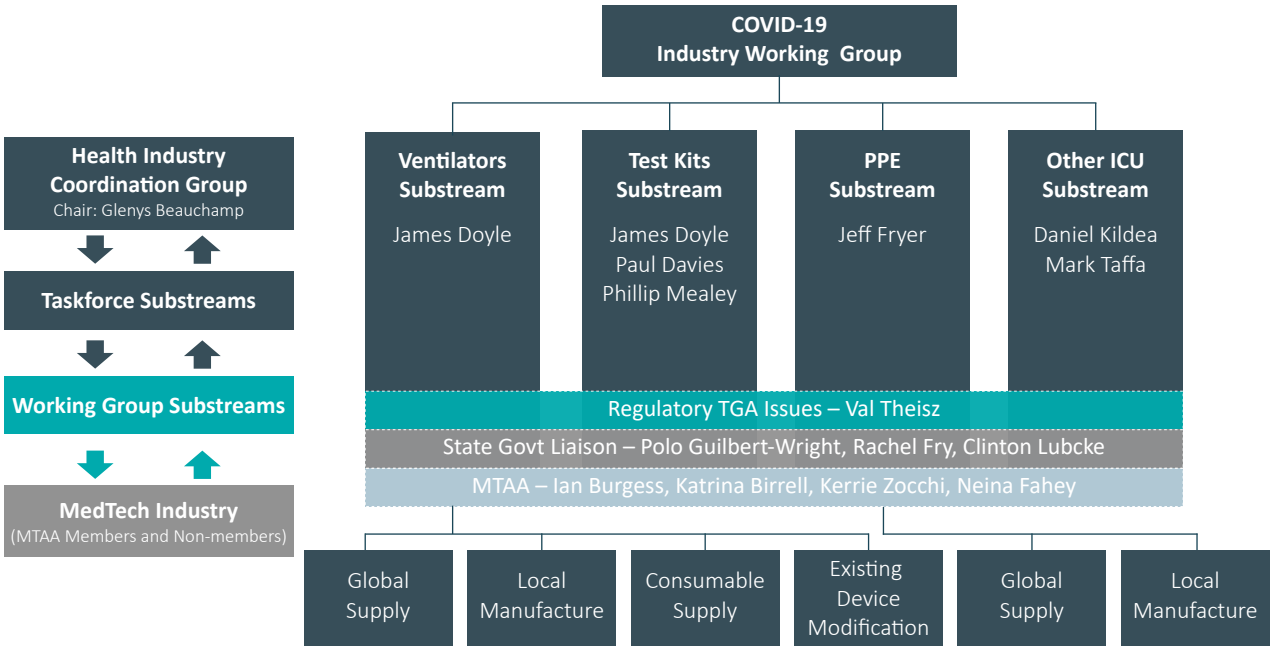
MTAA moved swiftly to set-up four Working Group substreams to cover Ventilators (Domestic and multinational), Testing / Test Kits, Personal Protective Equipment (PPE) and Other ICU supplies. Relevant companies from the industry were contacted to participate[1].

The purposes of each substream were to:

- map current local supply, observe demand and future supply chains
- identify gaps in supply and excess demand
- raise issues / barriers to supply chain fulfilment, including freight availability and cost and supply or allocation backlogs
- identify solutions to supply problems and demand mismatches

Each of the four substream groups involved industry and government representatives to ensure issues and challenges could be identified, elevated and resolved – at pace. Pathology Technology Australia (PTA), the peak body representing the IVD technology suppliers, was invited to join the Testing / Test Kit substream to represent the manufacturers and suppliers of the COVID-19 related test kits used in accredited pathology labs and at the point of care in Australia.

***Framework Taskforce and Working Group Substreams***




Each substream held meetings regularly with minutes taken and actions progressed. Outcomes of workstream activity were communicated up to the Chair and CEO of MTAA who maintained communication with Federal Government Ministers and were represented on the Federal Government Taskforce. Participants in the ventilator supply group were required to sign a Confidentiality Agreement.

[1] Note: see p.16 for further details of each Working Group substream and extensive list of industry participants.

In addition, due to the unique circumstances of the health emergency and the urgent need for input from across the medical technology sector, MTAA secured a temporary exemption from the Australian Competition & Consumer Commission to allow MTAA members to share competitive supply and cost information without breaching the *Competition and Consumer Act 2010* (see Attachment One).

As the issue of shortages of critical healthcare equipment, particularly PPE and ventilators, started to be reported by the media, a centralised media strategy was developed, with MTAA coordinating inquiries and responses on behalf of the industry.


***Teams call: Meeting of the Testing Kits Working Group***

# 3. Results delivered

Industry has responded in the public interest to a national health emergency; it has stepped-up and pitched-in to help Australia meet the COVID-19 challenge, establishing the 'Australia Model' of collaboration now being replicated around the world.

Medtech companies manufacturing and supplying products in Australia are deeply connected with the hospital system, with key links across infection control, ICU, anaesthetics and biomedical engineering. This allowed industry to play a critical role in ramping-up the supply and production of vital equipment including 3D-printed swabs for testing, circuit boards and electronic componentry and ventilators, including conversion kits for non-invasive machines to boost invasive ventilator capacity.

Industry has been integral in providing government with advice and an understanding of national ventilator installed base and capacity. Using their data sources, information on units installed, in which jurisdictions, numbers being serviced and numbers on order, industry has provided a cross-jurisdictional bridge of information that was not otherwise available.

With intense global pressure on manufacturing, supply chains and logistics infrastructure, industry worked exhaustively to ensure Australia secured its fair share of vital medical equipment, often absorbing dramatically increased raw material and freight costs in the process.

This commercial information has provided the baseline data that has underpinned planning for provision of ventilators across Australia against COVID-19 medical treatment forecasts; and understanding the gaps has allowed planning to meet expected demand and provide for a contingency supply.

Testing kits group member, 3DMEDiTech, repurposed production to 3D print medical swabs to meet shortages in the national stockpile. The Working Group linked ResMed and Grey Innovation to support production for both companies.

This included the sharing of proprietary designs and detailed reviews of supply chains to ensure both had adequate supply. The production ventilator group supported the introduction of local Australian manufacturers to support the production efforts of Grey Innovation: Circuitwise, 360 Knee and PD Medical all of whom repurposed production lines to meet the call for supporting Australian ventilator production.

The industry in Australia has met commitments to government, ensuring undertakings for supply of numbers of ventilators have been met, on time each month since March 2020.

3DMEDiTech™
Customised healthcare solutions

***3D printed nasopharyngeal swabs, manufactured by 3DMEDiTech at Port Melbourne, Victoria***

# 4. Key Lessons

## Collaboration with Industry is Essential

The Federal Government's Australian Health Sector Emergency Response Plan for COVID-19 (the Plan), published on 26 February 2020, did not include a specific role for the medical technology sector, either in its consultation framework or response planning. The one specific reference appears under 'communication and coordination':

"The management of a novel coronavirus outbreak will require governments, health sector industry and the community to work together."

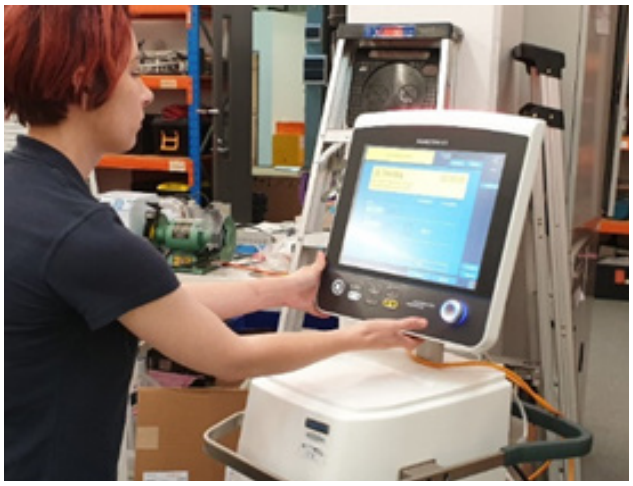
The Plan's lack of mechanisms to mobilise the capacities networks and expertise of the medical technology industry meant that institutional coordination mechanisms had to be invented 'on the fly' and under immense time pressure, involving industry executives and staff who were confronting the simultaneous crises of managing excess demand for some products and overburdened supply chains.

The fact that industry was able to stand-up a functional coordination mechanism that ensured Australia was able to expand ICU and ventilator capacity from domestic and overseas sources, obtain sufficient PPE through the pandemic first wave and resolve freight issues is testament to both the capabilities of the Australian medical technology sector and commitment to acting in the national interest.

In any viral pandemic – particularly pandemic influenza – we can anticipate demand surges for critical healthcare supplies including PPE, antivirals, mechanical ventilation, vaccines and ICU equipment, as well as supply constraints caused by simultaneous global demand. Future pandemic plans should learn from the experience of mobilising the health technology sector to aid the government's response.

## Data Gaps

The lack of a robust national system to track ventilator numbers is a critical lesson for future pandemic planning and preparedness. The various companies in Australia that sell and distribute ventilators were able to pool their collective information about numbers of devices in the field, numbers on order books (and an understanding of the logistics behind those orders – i.e. where they were coming from, nature of competing orders for same devices) and compare that information with health authorities who had information on demand, expected peaks and where the demand was localised. However, it was challenging to reconcile industry information with the variable numbers regarding ventilator availability in public and private hospitals.



***Hamilton Medical ventilators distributed, installed and supported by Australian medical device company Device Technologies based in Belrose, NSW.***

In other groups, while the industry representatives could quickly identify supply issues and capacity, excess demand was often difficult to reconcile with fundamental needs of hospitals and laboratories. Information on the consumption and depletion of supplies was harder to coordinate and complicated the task of mobilising supply.

Collaboration between suppliers (MTAA members and non-members) worked well, with an authentic willingness to come together. Input from trusted, legitimate industry players was a critical success factor in the 'fog of war' and global confusion in the rush to procure high quality equipment. The government-industry response to COVID-19 has generated consideration of the impact of a global marketplace on local supply chains – with every government around the world looking for ventilators in large numbers at the same time, with some countries having a bigger demand than others (e.g. US and UK vs Australia and Taiwan). The most in-demand components globally include electronics and circuitry, filters, breathing circuits, oximeters and certain raw materials.

## Role of the Regulator is Critical

The role of the regulator has emerged as critical and is a key learning for future planning. The TGA has been a key partner in the government-industry collaboration, providing rapid engagement with the sector and developing an accelerated approvals process. As an example, rapid approval of ventilator design variations allowed Australia to get earlier access to new products on the production line which may have otherwise gone to other countries.


***Ventilator circuit boards manufactured by Greater Western Sydney-based Circuitwise***

In addition to rapid approvals, the TGA took on a heavy workload around preparing and publishing regulatory and non-regulatory advice and guidance to industry. The TGA reports that over 2,200 new manufacturers entered the market from February to April this year, all requiring guidance.

Industry collaboration with the TGA assisted in the identification of unscrupulous players and well-intentioned amateurs and helped, along with Austrade and the Australian Border Force, to keep sub-standard, dangerous equipment from entering the market.

In terms of diagnostic tests, the need to expedite market entry of tests as quickly as they were made available inevitably resulted in market entry of unproven, and in some cases fraudulent, products. The TGA was quick to respond to obvious cases. However, in the case of rapid antibody tests, the quick availability of substandard products damaged the perceived potential value of higher quality tests from reputable manufacturers which arrived for evaluation in May, around the time antibody testing became a feasible epidemiological strategy.

The importance of a coordinated, comprehensive post-COVID-19 clean-up process has been identified, including action to accelerate withdrawal of approval of substandard diagnostic tests. This will ensure manufacturers, particularly the many new players, are following the standards and allow for the removal of any non-compliant manufacturers.

## States and Territories' Responses a Key Issue

At the height of the crisis, the state / territory responses were inconsistent, with some reacting more quickly than others and each having varying interactions with vendors and differing approaches to securing jurisdiction-specific supplies (targeted at current demand but also building supply buffer for future events).

In March, suppliers reported significant demand spikes from state / territory procurement agencies, local area health networks and individual hospitals, as well as receiving numerous requests to provide stock quantity reports. Orders were being placed for different purposes; some hospitals needed to use devices immediately, while other orders were to address expected future demand (stockpiling).

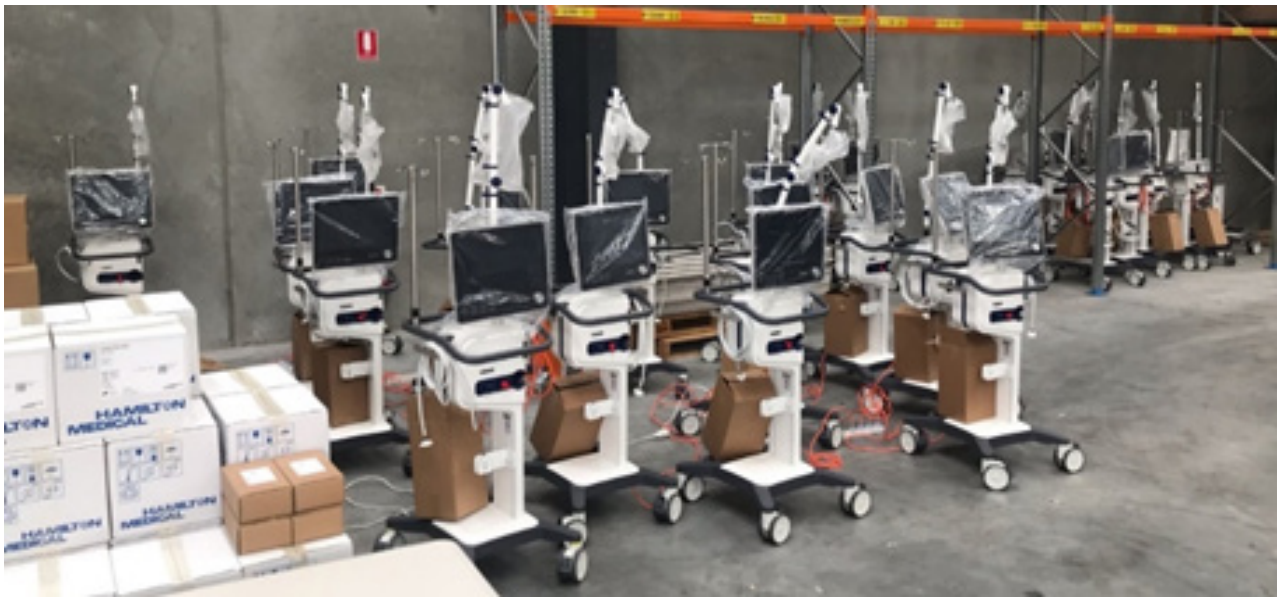
The lack of national uniform tracking and monitoring of ventilator devices, consumable utilisation and stock held across states added another layer of complexity for industry to manage in the scramble to procure equipment.

Including industry from the beginning and providing suppliers with visibility of state / territory high priority medical equipment needs can help prevent states and territories from effectively competing with each other to secure supplies. With timely industry input and intergovernmental coordination, all states and territories can get the medical supplies they need, to where they need them, when they need them.

## Communications Integration Matters

In the initial phase of the response, there were some unintended consequences as a result of differing communication strategies being pursued by government and industry. Conflicting and mixed messages were an ongoing concern, posing unforeseen risks. While steps were taken to centralise industry's messaging through the working groups, consistent messaging that didn't undermine supply options or perceptions of the magnitude of the challenge in Australia was a constant challenge. For example, messages aimed at reassuring the community regarding the supply of vital equipment can easily travel beyond Australia's borders and be misinterpreted by vital equipment suppliers in other countries an indicating that global supply can be diverted from Australia to other countries.

As different priorities emerged at different stages of the crisis, a key learning is to recognise the challenge of communication and consider ways the government can signal its requirements to industry via official correspondence and engagement, beyond what is reported in the media.




***Hamilton Medical ventilators distributed, installed and supported by Australian medical device company Device Technologies based in Belrose, NSW.***

## Border Issues and Biosecurity

With travel restrictions mandated by government including interstate travel, some companies who were part of the official response had difficulty in securing exemptions from travel restrictions for key personnel. For instance, one company could not get approval to move specialist personnel across borders in a timely manner (took five weeks), undermining industry's ability to respond.

Border issues also impact the movement of vital freight, including testing supplies, PPE and raw materials for ventilator production (into the country and interstate). These issues are exacerbated by the acute shortage of aircraft to transport freight, and consequent price hikes.

While challenging, the government-industry collaboration allowed for clear communication around necessary processes, the rapid generation of key email contacts that were shared around the groups and facilitated where possible the securing of priority space for vital equipment, including ventilators. Government agencies such as Austrade have played a key role in this facilitation.

## Pull Forward of Manufacturing

The long-term sustainability of the market and its suppliers is a concern. There must be recognition and consideration for the huge pull forward of manufacturing and supply pivoting to produce particular products in large quantities. There are also cash flow considerations as costs increased for raw materials, restocking and freight and logistics. When demand reduces and equipment is already in place there may not be any demand again for a number of years.

## Testing / test kits

Member companies of PTA and others in the sector worked quickly to provide a comprehensive audit of the installed base of COVID-19 related testing platforms; for Nucleic Acid Amplification Testing (NAT) including RNA extraction systems and detection systems; and for lab-based serology testing. Information was also provided on the range of mobile PCR platforms available. This demonstrates the value of having a group that can access such information so quickly and so comprehensively.

The audit demonstrated that our installed base was enough to enable increased testing within the existing accredited pathology laboratory infrastructure. However, if the COVID-19 caseload had been higher, meeting demand would have been challenging. Further, supply of some critical components required to complete testing lagged demand in some cases.

Understanding local manufacturing capability and the interaction with global supply chains to deliver increased diversity in supply of consumables is a key learning for supply of test kits in future pandemic scenarios which generate higher caseloads than has thus far been the case with COVID-19.

# 5. Recommendations

## Industry Involvement is Critical for Crisis Preparedness

Due to this effective partnership between government and industry, the medical technology sector is uniquely placed to consider strategies and initiatives for the future supply of ventilators and other medical equipment in a pandemic scenario. Holding real-world experience is the best way to understand current supply, potential gaps, international supply chains and logistic challenges.

Input from industry has been critical in informing government testing strategies and procurement of supplies, including:

- stocktakes of testing hardware platforms and suppliers
- promotion of government requests for information (RFIs), and expressions of interest (EOIs)
- advice on how the testing supply market operates
- recommendations of testing strategies

Any new or updated national pandemic preparedness plan must recognise the critical role of the medtech industry.

The experience of rapid mobilisation of the medical technology sector to aid the government's pandemic response has demonstrated that significant benefit would be derived from the establishment of a national industry medtech policy roundtable series, to provide a regular opportunity for the sector to engage with Department of Health and DISER.

High level government advisory committees that are being established should, wherever possible, include industry representatives.

## Establish a Cooperation Framework Agreement

The COVID-19 response has shown that industry and government collaboration can be mobilised quickly and tailored to fit the emergency scenarios.

So how best to prepare for a new pandemic that may emerge sometime in the future without over-engineering preparedness?

Rather than establish a new, permanent and costly bureaucratic structure, or a standalone government agency to oversee pandemic preparedness, a focus on mechanisms to bring various organisations, companies and State and Federal government representatives together swiftly to coordinate information and supply of vital equipment may be a more cost effective approach.

As part of that, it would be worthwhile identifying existing mechanisms, processes and resources which could be better leveraged to deal with potential future outbreaks. This could involve establishing a cooperation framework agreement which can trigger the sort of government-industry collaboration demonstrated during the COVID-19 response.

## National Map / Track System Required

It is important to create a robust and reliable system that can map the needs and supplies of medical equipment available in Australia at any given time. Uniform tracking and monitoring across states and territories and enhancing transparency will require data and input from industry, as well as cross-jurisdictional cooperation. Understanding the supply levels of ICU beds, ventilators and personal protective equipment, consumable utilisation and stock held in public and private hospitals in real-time can save precious time and ensure procurement efforts are informed and efficient. It can also ease pressure on global supply chains.

The same is true for testing kits. It is clear that suppliers hold important information that can better inform policy and strategy, such as:

- a fully integrated picture of the installed base of testing platforms
- the manufacturers stated device through-put and the current spare capacity
- local and global inventory of key consumables and knowledge of manufacturing capacity
- knowledge of new product development, performance and availability

Therefore, it is critical that in planning for future pandemics, direct input from the manufacturers and suppliers at a high level can make a meaningful difference.

The DISER Industry Taskforce team developed models for reporting ventilator numbers, surge capacity and consumable requirements which may be applicable in future pandemic responses. There is a need to build on this work, including engaging health research and data gathering capabilities within government, including the Australian Institute for Health and Welfare, to be able to execute rapid data gathering and dissemination to decision makers to minimise uncertainty and risk in resource decisions regarding pandemic response. State level data sharing is another element that would assist in differentiating between fundamental demand and stockpiling.

## Stockpile Procurement a Joint Effort

The design, maintenance and management of a national stockpile/s of drugs, vaccines, antidotes and essential medical equipment, including ventilators and their components and PPE, should be considered. Such an effort needs to consider the existing infrastructure supported by the Department of Health, through the National Medicines Stockpile which supplements state and territory stockpiles, and examine the role of government procurement while also leveraging the partnership between state and federal governments and industry to ensure a national solution is delivered efficiently.

Some thought could be given to strategies to ensure appropriate supply levels for test kits. This would include consideration of sovereign capabilities and local supply chain resilience, and alignment with global supply chains.

## Sovereign Manufacturing Capability

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.

It may be possible for Australia to play a key role in a coordinated international supply chain initiative as part of a future pandemic plan. Such an approach would allow Australia to leverage the broad scale industry collaboration that has just been demonstrated, to contribute certain components or assemble various items – and at the same time, access when needed, the number of ventilators and other critical healthcare equipment it requires for a timely and effective pandemic response.

It would be beneficial to better understand the role of government procurement in establishing sovereign capability and the interaction with supply chain resilience and diversification of source markets.

A scoping exercise is required to ascertain what it would take from a technology and workforce perspective to create this domestic industry versus Australia playing a part in a coordinated international supply chain which guarantees future supply of critical medical equipment. Such a scoping exercise will need to examine the potential market in business-as-usual scenarios as well as pandemic situations, and the market structure that would incentivise the investment in local manufacturing to service domestic and export markets.

## Workforce Capability

While medical equipment and technology are critical, healthcare is ultimately delivered by people. A detailed understanding of the health workforce should be a core component of future pandemic preparedness planning, ensuring we have the skilled workers and expertise to respond across all domestic jurisdictions, and the capacity to support service delivery in the broader Indo-Pacific region.

Additionally, understanding the broader MTP sector workforce is also critical in positioning Australia to meet the challenge of developing and retaining world-class talent who have industry experience in research, translation, clinical development and commercialisation of new medical technologies. It is noted that a new MRFF program operated by MTPConnect will conduct an extensive skills gap analysis of the MTP sector and will provide valuable insights for future pandemic planning.

***Ventilator company Draeger, Notting Hill Melbourne, adapting with virtual training for medical teams on using ventilators***

## R&D Commercialisation and Clinical Trials Infrastructure

Australia has a strong tradition of excellence in health and medical research. Our unique public and private system ensures all Australians have access to high quality care, our scientists, medical researchers and clinicians are world class, we have a culture of collaboration across disciplines generating a track record of translation and commercialisation success and we have a strong regulatory regime, robust intellectual property protection and strong commercial and trade links with growing Indo-Pacific markets.

Post COVID-19, an opportunity exists to leverage lessons learned from the government-industry collaboration to ensure timely development and deployment of new devices and software. The current focus on adaptive regulation should be continued and consideration be given to greater alignment between state and federal government approaches to innovation in the health system. Integration with funding systems for health services would also support faster access for consumers to new technology.

With an emphasis on evidence, within Australia's robust regulatory framework, there's scope to drive early adoption of medical technologies in the private health sector to collect post-market surveillance and performance data to inform policy, regulatory and funding decisions.

# 6. Working Group Snapshot

## Ventilators Supply and Production Working Group

The Ventilator Working Group was the largest group involving separate supply and production streams.

The Government selected ResMed as a local supplier and then set up a second domestic company to produce ventilators spearheaded by Grey Innovation.

| Ventilators Working Group – Supply | | | |
|---|---|---|---|
| Name | Organisation | Name | Organisation |
| Dr Alan Finkel | Australian Chief Scientist | Jane Urquhart | DISER |
| Alan Moreland | Draeger Australia Pty Ltd | Joanne Mulder | DISER |
| Allan Rowan | Getinge Australia Pty Ltd | Mark Storr | Avanos Medical Australia Pty Ltd |
| Andrew Crouch | Fisher & Paykel Healthcare Limited | Matt Moran | Philips Healthcare Australia |
| Andrew Wiltshire | Medtronic Australasia Pty Ltd | Matthew Tucker | GE Healthcare Australia Pty Ltd |
| Belinda Fraser | DISER | Maurice Ben-Mayor | Stryker Australia Pty Ltd |
| Catherine Delamare | ResMed Pty Ltd | Melissa Morabito | ResMed Pty Ltd |
| Celia Gleeson | Office of the Minister for Industry, Science and Technology | Neina Fahey | MTAA |
| Con Crighton | Medtronic Australasia Pty Ltd | Nic Schneider | Philips Healthcare Australia |
| Craig Stamp | Device Technologies Australia Pty Ltd | Patricia Isabelle | GE Healthcare Australia Pty Ltd |
| Daniel Popovski | Australian Chamber of Commerce | Scott Bradley | Philips Healthcare Australia |
| Duncan McIntyre | DISER | Scott Rodgers | Zoll Medical Australia Pty Ltd |
| Gino Grassia | DISER | Sharon Bennett | TGA |
| Glenys Beauchamp | DISER | Sue MacLeman | MTPConnect |
| Hon. Karen Andrews MP | Minister for Industry, Science and Technology | Tracey Duffy | TGA |
| Ian Burgess | MTAA | Vered Kieser | ResMed Pty Ltd |
| James Doyle | Stryker Australia Pty Ltd | Victor Li | Fisher & Paykel Healthcare Limited |

| Ventilators Working Group – Production | | | |
|---|---|---|---|
| Name | Organisation | Name | Organisation |
| Andrew Crocker | ResMed Pty Ltd | Lachlan Morris | Smiths Medical Australasia Pty Ltd |
| Bede O'Connor | 360 Knee Systems | Peter Deliopoulos | PD Medical |
| Belinda Fraser | DISER | Peter Lawless | NSW Health |
| David Hau | TGA | Peter Meikle | Grey Innovation Group Pty Ltd |
| Grant Mellor | Johnson & Johnson Pacific Pty Ltd | Ruth Coleman | Grey Innovation Group Pty Ltd |

| Ventilators Working Group – Production | | | |
|---|---|---|---|
| Name | Organisation | Name | Organisation |
| Iain McMillan | Enztec Australia Pty Ltd | Serena Ross | Circuitwise Electronics Manufacturing Australia |
| James Doyle | Stryker | Sharon Bennett | TGA |
| Jens Goennemann | AMGC | Sue MacLeman | MTP Connect |
| Joanne Mulder | DISER | | |
| Kathy Connell | Johnson & Johnson Pacific Pty Ltd | | |

## Testing Kits Working Group

This group focussed on identifying the COVID-19 related testing capability, including;

- The installed base in accredited pathology labs of the testing platforms involved in COVID-19 testing
- The manufacturer's quoted through-put of the platforms over a 24-hr period
- An estimate of the spare capacity of these platforms to complete COVID-19 testing
- Identifying potential gaps in supply of testing kits, extraction kits, swabs and transport media
- Providing advice on how some of these gaps can be closed and working with DISER and DH on these measures.

The group also provided useful information to the DISER on industry issues with border controls, freight and maintenance personnel logistics, and provided a mechanism for government to inform industry on initiatives to address these issues.

| Testing Kits Working Group | | | |
|---|---|---|---|
| Name | Organisation | Name | Organisation |
| Annie Arnett | Hologic (Australia) Pty Ltd | Lesley Andrew | DISER |
| Brandon Carp | Prac3 | Michelle McNiven | TGA |
| Clinton Lubcke | Baxter Healthcare Pty Ltd | Miranda Lello | DISER |
| Dean Whiting | Pathology Technology Australia | Paul Davies | Abbott Australasia Pty Ltd |
| Gary Lum | Department of Health | Phillip Mealey | Baxter Healthcare Pty Ltd |
| Grant Enders | 3DMEDiTech | Sam Chard | DISER |
| James Doyle | Stryker Australia Pty Ltd | Sue MacLeman | MTPConnect |
| Kristy Hardy | LifeHealthcare Pty Ltd | | |

# PPE Working Group

## PPE Workstream Update

### Industry Feedback to Taskforce

- 2 x supplier calls – provided feedback to Taskforce on:
  - Freight situation
  - Pricing surge
  - Manufacturing tightening
  - Export embargo's and product diversion

### National Stockpile

- RFQ released to supplier group for PPE products in huge quantities
- Three suppliers have responded and two more pending
- Raised issue of state vs national priority

### Consolidated View of Supply

WORK IN PROGRESS

- Attempting to build a consolidated view of PPE inventory, pending supply and potential demand & gap
- Have partnered with the Australasian Procurement and Construction Council to collect information from State Health procurement
- Has raised issues of co-ordination among stakeholder groups

### Local Manufacture

WORK IN PROGRESS

- Consistently passing on leads to the Taskforce substream responsible for local manufacture startup
- Some 30+ organisations attended a PPE roundtable on domestic manufacturing

## PPE Working Group

| Name | Organisation | Name | Organisation |
|---|---|---|---|
| Adam Lodge | Australian Safety Wholesalers | Katrina Birrell | MTAA |
| Andy Butler | Textor Technologies Pty Ltd | Kimberly Hill | Getz Healthcare Pty Ltd |
| Ben Chen | Multigate Medical Products Pty Ltd | Maurice Ben-Mayor | Stryker Australia Pty Ltd |
| Chris Selwa | MediGroup Australia Pty Ltd | Michael Goldberg | ResQ Devices |
| Dan Arona | MoInlycke Healthcare | Narelle Luchetti | DISER |
| Daniel Popovski | Australian Chamber of Commerce and Industry | Polo Guilbert-Wright | Edwards Lifesciences Pty Ltd |
| Darran Leyden | Whiteley Corporation | Richard Lord | 3M Health Care |
| David Tang | Mun Australia Pty Ltd | Scott Joyce | Bastion Pacific |
| James Pearson | Australian Chamber of Commerce and Industry | Sharon Bennett | TGA |
| Jane Saphin | 3M Health Care | Simon Waters | TGA |
| Jason Aldworth | 3DMEDiTech | Sue MacLeman | MTPConnect |
| Jeff Fryer | Medtronic Australasia Pty Ltd | Teresa Scott | Australasian Procurement and Construction Council |
| John Anderson | Bastion Pacific | Tom Ryan | DISER |
| John Rochman | iSmile Group | William Monaghan | NT Chief Procurement officer |
| Joshua Eastaugh | Haines Medical Australia | | |

## Other ICU Working Group

The purpose of the ICU emerging products Working Group:

- Identifying ICU equipment (excluding ventilators & PPE) that is, or risks being, in critically short supply due to COVID-19 demands
- Understanding industry capability to meet health service peak pandemic requirements

The work of the ICU Working Group is to:

1. Identify the basic equipment requirements for a high dependency area that are needed to repurpose an area for the care of critically ill COVID-19 patients, and identify which companies supply that equipment; (spikes in demand, advice from ICU leads in states and territories and ICU experts – need help sourcing contacts)
2. Quantify the stock companies already have, and quantify the stock they can supply in a short period of time;
3. Determine the expected quantity of equipment will be required by state and territory governments as we approach the peak phase of the pandemic;
4. Engage in problem solving supply chain issues, including consideration of both traditional and non-traditional sources, in order to meet expected demand.

| Other ICU Working Group | | | |
|---|---|---|---|
| Name | Organisation | Name | Organisation |
| Alan Moreland | Draeger Australia Pty Ltd | Mark Taffa | Horten Medical |
| Anthony Keogh | Teleflex Medical Australia Pty Ltd | Martin Monaghan | Fresinius Kabi Australia Pty Ltd |
| Ben Edwards | GE Healthcare Australia Pty Ltd | Matt Malone | Stryker Australia Pty Ltd |
| Bruce Peatey | Hillrom Pty Ltd | Matt Tucker | GE Healthcare Australia Pty Ltd |
| Daniel Kildea | Johnson & Johnson Pacific Pty Ltd | Matthew Moran | Philips Healthcare Australia |
| Daniel Popovski | Australian Chamber of Commerce and Industry | Michael Luxton | Arjo |
| Daniela Croce | DISER | Michele Graham | DISER |
| Elspeth Kay | TGA | Nic Schneider | Philips Healthcare Australia |
| Flor Maldonado | Smiths Medical Australasia Pty Ltd | Nick Adam | Smiths Medical Australasia Pty Ltd |
| Francesca Astolfi | DISER | Patricia Isabelle | GE Healthcare Australia Pty Ltd |
| Georgia Psarros | Baxter Healthcare Pty Ltd | Paul Davies | Abbott Australasia Pty Ltd |
| Jarrad White | Stryker Australia Pty Ltd | Phillip Kelly | Edwards Lifesciences Pty Ltd |
| Jason Aldworth | 3DMEDiTech | Rachael Hook | B Braun Australia Pty Ltd |
| Katrina Birrell | MTAA | Sam Wegg | Medtronic Australasia Pty Ltd |
| Kelley Wiggins | DISER | Scott Bradley | Philips Healthcare Australia |
| Kensi Naicker | BD | Sue MacLeman / Dan Grant | MTPConnect |
| Leanne Smith | Teleflex Medical Australia Pty Ltd | Veronica Heard | DISER |
| Mark Storr | Avanos Medical Australia Pty Ltd | Xin-Lin Goh | TGA |

# 7. ACCC authorisation

AUSTRALIAN COMPETITION & CONSUMER COMMISSION[2]

## Medical Technology Association of Australia – Application for authorisation AA1000479 Interim authorisation decision 17 April 2020

### Decision

1. The Australian Competition and Consumer Commission (the **ACCC**) has granted interim authorisation in respect of the application for authorisation AA1000479, lodged by the Medical Technology Association of Australia (the **MTAA**) on 14 April 2020.
2. The MTAA has applied for authorisation on behalf of itself, its members (**MTAA members**) and other relevant businesses in the medical technology industry (**relevant non-members**) (together, the **Applicants**), to enable them to implement a coordinated strategy in relation to the supply of medical equipment and supplies in response to the COVID-19 pandemic.
3. The ACCC initially granted interim authorisation to the Applicants on 25 March. Subsequently the MTAA has amended its application, and sought interim authorisation for the conduct described in the amended application. The ACCC has revoked the interim authorisation granted on 25 March, and substituted this conditional interim authorisation.
4. The ACCC has granted interim authorisation for the conduct described at paragraph 7 below, subject to the conditions described at paragraph 18.
5. Interim authorisation commences immediately and remains in place until it is revoked or the date the ACCC's final determination comes into effect.

### The application for authorisation

6. The MTAA is the national association representing companies in the medical technology industry, representing manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. 1 MTAA members distribute a wide range of medical technology, which includes ICU ventilators, COVID-19 testing kits and personal protective equipment.
7. The MTAA is seeking authorisation for its members, as well as businesses that supply or distribute relevant medical equipment who are not MTAA members. A list of these parties is at **Attachment A**. The MTAA is also seeking authorisation for future MTAA members and relevant non-members, on the basis that the relevant parties and products may expand as the Federal Government's response to the crisis evolves and information relating to new medical equipment or products is required.

[2] Note – this appendix is an illustrative copy of an ACCC authorisation

8. Authorisation is sought to make and give effect to arrangements, and to exchange information, between the MTAA, MTAA members and non-members for the purposes of:
    a. sharing information regarding:
        i. available stock and inventory levels, including parts and inputs;
        ii. actual or likely quantities of stock, parts and / or inputs that can be obtained through existing supply channels,
        iii. new sources of supply and potential orders or quantities;
        iv. projected or likely expected demand;
        v. potential delays or failures in the services of third party domestic and international transport, freight and logistics providers;
        vi. freight costs; and
        vii. opportunities to increase domestic manufacturing,

        for a range of medical equipment and supplies, being:

        viii. initially, ICU ventilators, COVID-19 testing kits and Personal Protective Equipment; and
        ix. the full range of medical equipment, consumables and technology used in the treatment of intensive care patients; and
        x. other medical equipment and consumables that are required to address the increased demands on the health system arising from the COVID-19 crisis in respect of which there are actual or potential supply constraints because of domestic or global supply shortages or the impact of freight and logistics;
    b. coordinating procurement of inputs, manufacturing and coordinating and allocating the fulfilment of orders and supply requests between suppliers;
    c. prioritising certain requests for supply as nominated by the Federal Government, State and Territory Governments and relevant health authorities; and
    d. working together to respond to tenders or requests for supply (including sharing information or joint tenders).

(The Proposed Conduct)

9. The Federal Government has advised MTAA that, due to the impact of COVID-19, it is seeking to secure adequate supply of medical equipment necessary for the treatment of COVID-19 patients. The MTAA submits that the Proposed Conduct is required to respond to the Federal Government Department of Health request that the MTAA coordinate with its members to identify sources of supply for medical equipment and to provide advice to government regarding any constraints or obstacles to securing this supply.

10. In its original application, the MTAA submitted that it anticipated, in the short term, the Proposed Conduct would only include the information sharing conduct outlined in 7(a). In submitting the amended application for authorisation the MTAA advised that as the national response to the COVID-19 pandemic has developed, it is now necessary for MTAA members and non-members to engage in the coordinating of manufacturing and procuring inputs as outlined in 7(b) above. MTAA states that, given the fluidity and uncertainty of the current situation and the need to implement any further measures quickly, it is also seeking authorisation of the conduct described at 7 (c)-(d) as it considers that it may have to engage in such conduct as the COVID-19 situation progresses. The MTAA anticipates that State, Territory and Federal health authorities will determine the manner in which they require supplies of necessary medical equipment to be made by the MTAA members and non-members rather than those matters being determined or agreed among suppliers.

11. The MTAA submits that it is seeking authorisation of the conduct described in paragraphs 7 (b)-(d), on the basis that the MTAA will provide notice to the ACCC if they are to engage in these parts of the Proposed Conduct. The MTAA also proposes to provide notice to the ACCC of new MTAA members and non-members that are or that are expected to become involved in the Proposed Conduct as the response to the COVID-19 situation evolves.

12. The MTAA is seeking authorisation for 12 months from the ACCC's grant of final authorisation.

## The authorisation process

13. Authorisation provides protection from legal action for conduct that may otherwise breach the competition provisions of the *Competition and Consumer Act 2010* (Cth) (the **Act**). Broadly, the ACCC may grant authorisation if it is satisfied that the benefit to the public from the conduct outweighs any public detriment, including from a lessening of competition. The ACCC conducts a public consultation process to assist it to determine whether proposed conduct results in a net public benefit.

## Interim authorisation

14. The ACCC may, where it considers it appropriate, grant an interim authorisation which allows parties to engage in proposed conduct while the ACCC is considering the substantive application.

15. The MTAA requested urgent interim authorisation for the Proposed Conduct to allow the Applicants to start coordinating to address supply shortages for critical medical supplies and equipment, as well as provide advice to the Federal Government, State and Territory Governments and relevant health agencies relating to supply of medical equipment, including areas of current or anticipated shortage and supply constraints.

## Consultation

16. The ACCC has not conducted a public consultation process in respect of the request for interim authorisation in light of the compelling nature of the public benefits likely to result from the request for interim authorisation.

17. The ACCC will shortly commence a public consultation process on the substantive application for authorisation, and details regarding how to make a submission will be available on the ACCC's authorisations public register.

## Conditions of authorisation

18. Interim authorisation is granted subject to the following conditions:

    a. Notification of future parties

        - The MTAA must promptly notify the ACCC of any new Members and non-members that will be involved in the conduct for which authorisation is granted.

    b. Notification of proposed conduct

        - The MTAA must use all reasonable endeavours to give the ACCC 7 days' notice if it is proposed that Applicants will engage in the type of conduct described in paragraph 8(b), (c) and (d).
        - In urgent circumstances where it is not reasonably practicable to provide 7 days' notice, the MTAA may give shorter notice but in each such urgent case must provide at least 1 business day notice before engaging in the conduct.

    c. Reporting requirements

        - The MTAA must provide regular updates to the ACCC regarding any material decisions and developments in relation to the Proposed Conduct, including any material contracts, arrangements made or understandings entered into as part of conduct by Applicants of the type described in paragraph 8(b), (c) and (d).

    d. Provision of any further information

        - The MTAA, any MTAA member and any non-member involved in the conduct which is authorised must promptly provide any further information about the conduct being engaged in under this interim authorisation that the ACCC requests from time to time.

## Reasons for decision

19. In granting interim authorisation, the ACCC recognises the urgency of the request for interim authorisation in light of the increased demand on the health system due to the COVID-19 pandemic.

20. The ACCC notes that the Applicants have advised that the extent to which the conduct is engaged in will be determined by State, Territory and Federal health authorities who will determine the manner in which they require supplies of necessary medical equipment to be made by the MTAA members and non-members rather than those matters being determined or agreed among suppliers.

21. The ACCC also notes that the significant number of participants in the conduct means the ACCC cannot at this time form a view as to the likely long term effects of the conduct to on the competitive dynamics in a market in Australia. However, there are a number of factors which means markets will be able to return to substantially their current state once the emergency circumstances subside. In particular:

    - the Proposed Conduct, and interim authorisation itself, is a temporary measure. Authorisation is only sought for 12 months from the date of the ACCC's final determination and the Proposed Conduct can be discontinued in the event that the effects of the pandemic subside at an earlier date.
    - the ACCC has granted interim authorisation subject to the condition that the MTAA will regularly update the ACCC regarding any material developments in relation to the Proposed Conduct.
    - the Proposed Conduct will be influenced by what Commonwealth and State health authorities need to supply necessary equipment in response to the COVID-19 crisis.
    - the information that will be shared under the Proposed Conduct will predominantly be time-limited, so will lose relevance following the cessation of the Proposed Conduct.
    - the Proposed Conduct does not extend to setting or agreeing prices which will remain the discretion of each supplier.
    - the ACCC may review its decision to grant interim authorisation at any time, including in response to feedback as the Proposed Conduct is rolled out. If relevant industry participants have concerns regarding the Proposed Conduct during interim authorisation, they are encouraged to advise the ACCC.

22. There are likely to be significant public benefits including by allowing MTAA, its members and non-members to:

    - coordinate their manufacture and supply activities and exchange information so that areas of supply shortage and constraint to be addressed more quickly and effectively to assist Federal, State and Territory governments to respond to the COVID-19 crisis.
    - effectively advise Federal, State and Territory governments on the supply of medical equipment which is essential to ensuring coordinated and effective response to this unprecedented international public health crisis.

23. The ACCC notes that the Applicants will notify the ACCC if the Applicants engage in the conduct outlined at 7 (b) – (d) and will also notify the ACCC as new MTAA members and non-members engage in the Proposed Conduct. Given the potential breadth of the Proposed Conduct, the ACCC has incorporated these notifications within the condition at paragraph 18.

24. The ACCC is satisfied that the extraordinary circumstances of the COVID-19 crisis and the importance of the supply of medical material to addressing the crisis warrant the granting of interim authorisation.

### Reconsideration of interim authorisation

25. The ACCC may review a decision on interim authorisation at any time, including in response to feedback raised following interim authorisation. The ACCC's decision in relation to the interim authorisation should not be taken to be indicative of whether or not the final authorisation will be granted.

## Attachment A – Current Parties to the Proposed Conduct

### MTAA Members

| Organisation | Organisation | Organisation |
|---|---|---|
| 3D-Matrix Medical Technology Pty Ltd | Culpan Medical Australia Pty Ltd | Medi Press |
| 3DMEDiTech | Device Technologies Australia Pty Ltd | Medtronic Australasia Pty Ltd |
| 3DMorphic Pty Ltd | Edwards Lifesciences Pty Ltd | MicroPort CRM Pty Ltd |
| 3M Australia Pty Ltd | Elekta Pty Ltd | Molnlycke Healthcare |
| Abbott [Vascular] Australasia | Exactech Australia | NeedleCalm Pty Ltd |
| Abbott Medical Australia Pty Ltd | Fresenius Kabi Australia Pty Ltd | Nevro Medical Pty Ltd |
| Alcon Laboratories (Australia) Pty Ltd | Fresenius Medical Care Australia Pty Ltd | NL-Tec Pty Ltd |
| Allergan Australia Pty Ltd | Gamma Gurus | Olympus Australia Pty Ltd |
| AlphaXRT Ltd | Gel Works Pty Ltd | Paragon Therapeutic Technologies |
| Amplifon Australia | Getz Healthcare Pty Ltd | Prism Surgical Designs Pty Ltd |
| Analytica Pty Ltd | Grey Innovation | Roche Diabetes Care Australia Pty Ltd |
| APNE Surgical Pty Ltd | Hemideina | Smith & Nephew Pty Ltd |
| Australasian Medical & Scientific Ltd | Hillrom Pty Ltd | Smiths Medical Australasia Pty Ltd |
| Australian Dermatology Equipment | Hologic (Australia) Pty Ltd | Spectrum Surgical Pty Ltd |
| Avanos Medical Australia Pty Ltd | Horten Medical | Stryker Australia Pty Ltd |
| B Braun Australia Pty Ltd | Johnson & Johnson Medical Pty Ltd | Teleflex Medical Australia Pty Ltd |
| Bard Australia Pty Ltd | KLS Martin Australia Pty Ltd | Terumo Australia Pty Ltd |
| Bausch & Lomb (Australia) Pty Limited | Laminar Air Flow Pty Ltd | Tomi Australia Pty Ltd |
| Baxter Healthcare Pty Ltd | LifeHealthcare Pty Ltd | Tunstall Australasia Pty Ltd |
| Biotronik Australia Pty Ltd | LivaNova Australia Pty Ltd | Varian Medical Systems Australasia Pty Ltd |
| Boston Scientific Pty Ltd | Materialise Australia Pty Ltd | Vision RT Australia Pty Ltd |
| Brainlab Australia Pty Ltd | Medacta Australia Pty Ltd | W. L. Gore and Associates (Aust) Pty Ltd |
| ConMed Australia | MED-EL Implant Systems Australasia Pty Ltd | Wright Medical Australia |
| Cook Australia Pty Ltd | Medical Specialties Australia Pty Ltd | Zimmer Biomet |
| Corin (Australia) Pty Ltd | Medigroup Australia Pty Ltd | |

## Non-Members

| Organisation | Organisation | Organisation |
|---|---|---|
| Australian Business Mobiles (NSW) Pty Ltd | Multigate Medical Products Pty Ltd | GE Healthcare Australia Pty Limited |
| Australian Safety Wholesalers Pty Ltd | Mun Australia Pty Limited | Philips Healthcare Australia |
| iSmile Group | ResMed Pty Ltd | Vapotherm Inc |
| Mo Milling Pty Ltd | Draeger Australia Pty Ltd | Whiteley Corporation Pty Ltd |

## Members of Pathology Technology Australia as at 23 March 2020 (who are not MTAA Members)

| Organisation | Organisation | Organisation |
|---|---|---|
| Abacus dx Pty Ltd | ESL Biosciences Australia (2012) Pty Ltd | QIAGEN Pty Ltd |
| Abbott Australiasia Pty Ltd | Grifols Australia Pty Ltd | Radiometer Pacific Pty Ltd |
| Agilent Technologies Australia Pty Ltd | Illumina Australia Pty Ltd | Roche Diagnostics Australia Pty Ltd |
| Ascencia Pty Ltd | Integrated Sciences Pty Ltd | Siemens Healthcare Pty Ltd |
| Astral Scientific Pty Ltd | Life Bioscience Pty Ltd | SJ Alder Pty Ltd |
| Becton Dickinson Pty Ltd | Lumos Diagnostics Holdings Pty Ltd | SpeeDx Pty Ltd |
| Binding Site Pty Ltd | Merck Millipore Australia Pty Ltd | Sysmex Australia Pty Ltd |
| bioMérieux Australia Pty Ltd | MP Biomedicals Australasia Pty Ltd | Tecan Australia Pty Ltd |
| Bio-Rad Laboratories Pty Ltd | Paragon Therapeutic Technologies Pty Ltd | ThermoFisher Scientific Australia Pty Ltd |
| Cepheid Holdings Pty Ltd | PerkinElmer Pty Ltd | Trajan Scientific Australia Pty Ltd |
| Diagnostica Stago Pty Ltd | Pro-Health Asia Pacific Pty Ltd | Werfe Australia Pty Ltd |

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# Information


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