



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

Produced in association with

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Medical Technology
ASSOCIATION OF AUSTRALIA

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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

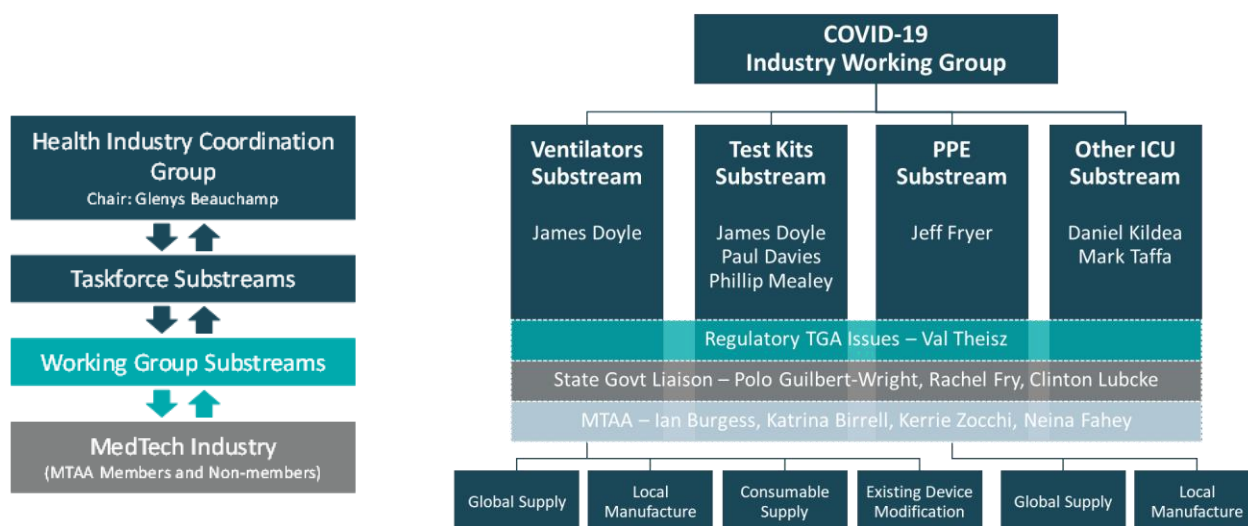
MTAA moved swiftly to set-up four Working Group substreams to cover Ventilators (Domestic and multinational), Testing/Test Kits, Personal Protective Equipment (PPE) and Other ICU supplies. Relevant companies from the industry were contacted to participate¹

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. 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

¹ Note: see p.14 for further details of each Working Group substream and extensive list of industry participants).

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.

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



3DMEDiTech™
 Customised healthcare solutions

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.

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.

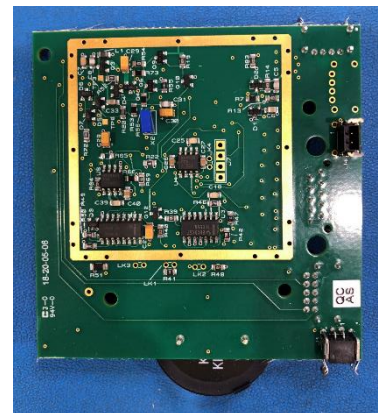
Hamilton Medical ventilators distributed, installed and supported by Australian medical device company Device Technologies based in Belrose, NSW.



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 as 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	Geringe 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

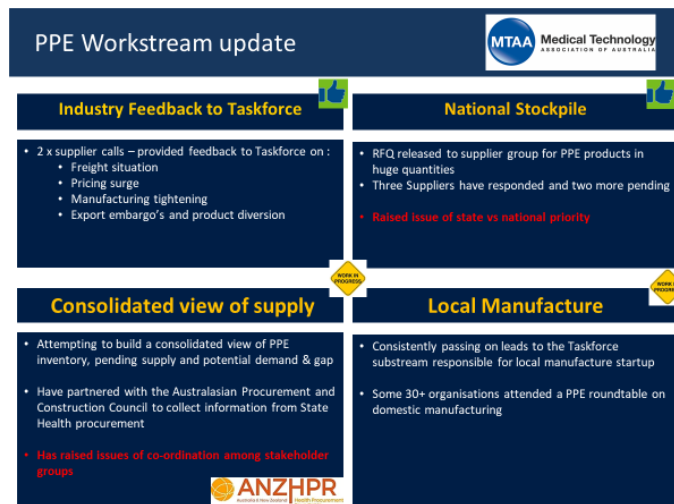
This group focussed on identifying the COVID-19 related testing capability, including;

- 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 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	Molnlycke 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	Fresenius 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
Elsbeth 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
COMMISSION²

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

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

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.

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:

- (1) 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.

(2) 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.

(3) 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).

(4) 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

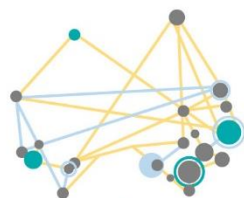
Organisation	Organisation	Organisation
Australian Dermatology Equipment	Hologic (Australia) Pty Ltd	Spectrum Surgical Pty Ltd
Avanos Medical Australia Pty Ltd	Horten Medical	Stryker Australia Pty Ltd
B Braun Australia Pty Ltd	Johnson & Johnson Medical Pty Ltd	Teleflex Medical Australia Pty Ltd
Bard Australia 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 Australasia 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



MTPConnect

MedTech and Pharma Growth Centre

CONTACT US FOR FURTHER INFORMATION

Phone +61 3 7019 0917

Email info@mtpconnect.org.au

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Melbourne VIC 3000
Australia

NSW Sydney Hub

Level 5
J12 School of IT
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1 Cleveland Street
Darlington
NSW 2006
Australia

QLD Brisbane Hub

Translational
Research Institute
Level 7
37 Kent Street
Woolloongabba
QLD 4102
Australia

VIC Melbourne Hub

Monash University
Clayton
VIC 3168
Australia

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The University
of Western Australia
Harry Perkins
Institute of Medical
Research Building
QELI Medical Centre
6 Verdun Street
Nedlands WA 6009
Australia

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