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14 April 2020

Ms Danielle Staltari  
 Director, Adjudication  
 Australian Competition and Consumer Commission  
 23 Marcus Clarke Street  
 Canberra ACT 2601  
**Danielle.Staltari@accc.gov.au**

Dear Ms Staltari

**Medical Technology Association of Australia: amendment to application for authorisation and interim authorisation**

We act for the Medical Technology Association of Australia Limited (**MTAA**).

We refer to MTAA's application for authorisation and urgent interim authorisation dated 23 March 2020 (**Application**), and the ACCC's decision to grant interim authorisation dated 25 March 2020 (**Interim Authorisation Decision**). Unless otherwise stated, capitalised terms used in this letter have the same meaning as in the Application.

**Proposed amendments to scope of Proposed Conduct**

In light of feedback received from Members, the MTAA seeks certain amendments to expand the scope of Proposed Conduct in respect of which authorisation and interim authorisation has been sought.

The proposed amendments are set out in **Schedule 1**, and the Applicants now seek authorisation and interim authorisation for the Proposed Conduct, as amended.

The amendments seek to expand the scope of the Proposed Conduct by:

1. expanding the scope of information sharing (in paragraph 8(a) of the Application) to include sharing information relating to:
  - (a) parts, inputs used in the manufacture of certain medical equipment such as respirators and consumables;
  - (b) projected or likely expected demand for medical supplies;
  - (c) potential delays or difficulties in obtaining the services of third party domestic and international transport, freight and logistics providers involved in freight of medical supplies, inputs and consumables; and
  - (d) freight costs.
2. allowing the Applicants to coordinate or agree on allocation in the procurement of inputs and components in manufacturing activities for medical supplies.

**Rationale for amendments**

3. At paragraph 20 of the Interim Authorisation Decision, the ACCC recognised that:

*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.*
4. The MTAA submits that the further aspects of information sharing and coordination of procurement of inputs and manufacturing activities described above are consistent with the significant public benefits identified for the original application.
  5. Component parts and inputs are raw components to be ordered and used in the manufacturing of medical equipment, and consumables refer to "single use" equipment such as testing kits, swabs, filters, valves, circuits, tubes, oximeters, masks and wipes (as distinct from equipment such as respirators with a longer useful life). While the MTAA considers that such items would be captured by the term "medical equipment and supplies" in paragraph 8 of the Application, some MTAA Members and Non-Members have requested that parts, inputs and consumables are expressly included within the definition of Proposed Conduct for the sake of clarity.
  6. Freight and logistics costs are an important component of cost structures for medical equipment since the majority of such equipment supplied in Australia is imported from overseas. MTAA understands that some government groups are requesting information from MTAA Members regarding the costs of medical equipment excluding freight as they are offering to collect using their own logistics or distribution networks. In addition, given the urgency and importance of ensuring ongoing medical equipment supplies into Australia and the impact of COVID-19 on freight and logistics networks internationally and within Australia, it is necessary for MTAA Members and Non-Members to share information on potential delays or failures in the services of third party domestic and international transport, freight and logistics providers. Sharing such information will allow suppliers to better respond to government agency information requests and ensure that medical equipment can be delivered in a cost effective manner in the current climate.
  7. One of the key strategies of the Commonwealth and State and Territory Governments' response to the COVID-19 pandemic has been to urgently procure additional supplies of certain medical devices. For example, one of the highest priorities has been to source additional ventilators for use in intensive care units. Currently, in the absence of a vaccine or other proven treatment options, use of ventilators is one of the very few effective medical interventions available to treat patients with acute COVID-19 who are experiencing acute respiratory failure. One of the challenges involved in urgently procuring additional supplies of medical devices such as ventilators for use in Australia is the competing demand from other countries for the same devices.
  8. One of the strategies to address this issue has been to fast track manufacturing of required medical devices in Australia. Enabling MTAA Members and Non-Members to coordinate their manufacturing activities, including the procurement of parts and inputs, for such medical equipment is critical to ensuring ongoing medical equipment supply in response to the COVID-19 pandemic. The MTAA notes that the public benefits arising from this form of collaboration is expressly contemplated in paragraph 20 of the Interim Authorisation Decision.





9. To maximise the manufacture of certain medical devices (such as ventilators), device manufacturers may wish to discuss and agree with competitors about manufacturing matters such as:
  - whether they can share parts, inputs or consumables that one manufacturer may require but one manufacturer may have in excess;
  - whether they can share alternative sources of parts, inputs or consumables in the event that one manufacturer's usual suppliers of parts, inputs or consumables have supply issues;
  - where there may be supply issues, have joint discussions with suppliers to determine if changing ordering patterns could assist suppliers to produce overall more parts, inputs or consumables that can be used to increase overall manufacture of medical devices. For example, if different manufacturers require suppliers to produce parts to certain specifications, discussing with the supplier whether ordering to common specifications would assist the supplier to produce more parts overall;
  - allocating manufacturing between manufacturers to increase overall production volumes and potentially jointly fill orders, for example, one manufacturer agreeing to manufacture one model of ventilator and one manufacturer agreeing to manufacture another.
10. The application for variation is made in order to remove any ambiguity about whether the 'Proposed Conduct' extends to coordination among competitors at the manufacturing level.
11. It remains the case that the extent to which the Proposed 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. 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 coordination of manufacturing activities and the procurement of inputs. For this reason, the MTAA hereby notifies the ACCC that, subject to the ACCC's decision in relation to this amendment, the scope of the Proposed Conduct will expand to include the conduct set out in paragraphs 8(a) and 8(b) of the definition of Proposed Conduct (as varied).

#### **Reporting condition**

12. If the ACCC proposes to impose a condition on any interim authorisation that requires reporting of relevant conduct, the MTAA would not oppose a condition requiring the reporting of

- (a) any conduct that falls into paragraphs 8(b),(c) and (d) in the attached Schedule 1 within 7 days of the agreement or arrangement concerned being made or entered into, and
  - (b) the inclusion of any new MTAA Members or Non-Members to be covered by the terms of the authorisation.
13. Since the Application was lodged, the MTAA has identified new Non-Members who require coverage by the terms of the authorisation and interim authorisation. A revised list of MTAA Members and Non-Members is set out in **Schedule 2**.

**Timing of ACCC consideration**

14. We are instructed to request an urgent consideration of the application for variation given that it relates to the manufacture of ventilators for the purposes of ensuring Australian hospitals have sufficient supplies in the event of a spike in ICU cases. Our client would be grateful for the application to be turned around in the shortest time possible to maximise the number of ventilators which can be manufactured through such cooperation.

Please let us know if you have any questions.

Yours sincerely

**Michael Corrigan, Partner**

**Justin Chen, Lawyer**

Your ref: AA1000479-1  
Our ref: 187/21208

## Schedule 1 - Proposed amendment to scope of Proposed Conduct

This schedule sets out the proposed amendments to the scope of Proposed Conduct (in mark up against the definition of Proposed Conduct set out at paragraph 8 of the Application).

### Proposed conduct to be authorised

8. The Proposed Conduct includes making and giving effect to agreements and arrangements, and exchanging 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;
    - ~~(iii)(vi)~~ freight costs; and
    - ~~(iv)(vii)~~ opportunities to increase domestic manufacturing,

for a range of medical equipment and supplies, being:

    - ~~(v)(viii)~~ initially, ICU ventilators, COVID-19 testing kits and Personal Protective Equipment; and
    - ~~(vi)(ix)~~ the full range of medical equipment, consumables and technology used in the treatment of intensive care patients; and
    - ~~(vii)(x)~~ other medical equipment and consumables that ~~is~~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).

**Schedule 2 - List of MTAA Members and Non-Members****MTAA Members**

3D-Matrix Medical Technology Pty Ltd
3DMEDiTech
3DMorphic Pty Ltd
3M Australia Pty Ltd
Abbott [Vascular] Australasia
Abbott Medical Australia Pty Ltd
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia Pty Ltd
AlphaXRT Ltd
Amplifon Australia
Analytica Pty Ltd
APNE Surgical Pty Ltd
Australasian Medical & Scientific Ltd
Australian Dermatology Equipment
Avanos Medical Australia Pty Ltd
B Braun Australia Pty Ltd
Bard Australia Pty Ltd
Bausch & Lomb (Australia) Pty Limited
Baxter Healthcare Pty Ltd
Biotronik Australia Pty Ltd
Boston Scientific Pty Ltd
Brainlab Australia Pty Ltd
ConMed Australia
Cook Australia Pty Ltd
Corin (Australia) Pty Ltd
Culpan Medical Australia Pty Ltd
Device Technologies Australia Pty Ltd
Edwards Lifesciences Pty Ltd
Elekta Pty Ltd
Exactech Australia
Fresenius Kabi Australia Pty Ltd
Fresenius Medical Care Australia Pty Ltd
Gamma Gurus
Gel Works Pty Ltd
Getz Healthcare Pty Ltd
Grey Innovation



Hemideina
Hillrom PTY LTD
Hologic (Australia) Pty Ltd
Horten Medical
Johnson & Johnson Medical Pty Ltd
KLS Martin Australia Pty Ltd
Laminar Air Flow Pty Ltd
LifeHealthcare Pty Ltd
LivaNova Australia Pty Ltd
Materialise Australia Pty Ltd
Medacta Australia Pty Ltd
MED-EL Implant Systems Australasia Pty Ltd
Medical Specialties Australia Pty Ltd
Medigroup Australia Pty Ltd
Medi Press
Medtronic Australasia Pty Ltd
MicroPort CRM Pty Ltd
Molnlycke Healthcare
NeedleCalm Pty Ltd
Nevro Medical Pty Ltd
NL-Tec Pty Ltd
Olympus Australia Pty Ltd
Paragon Therapeutic Technologies
Prism Surgical Designs Pty Ltd
Roche Diabetes Care Australia Pty Ltd
Smith & Nephew Pty Ltd
Smiths Medical Australasia Pty Ltd
Spectrum Surgical Pty Ltd
Stryker Australia Pty Ltd
Teleflex Medical Australia Pty Ltd
Terumo Australia Pty Ltd
Tomi Australia Pty Ltd
Tunstall Australasia Pty Ltd
Varian Medical Systems Australasia Pty Ltd
Vision RT Australia Pty Ltd
W. L. Gore and Associates (Aust) Pty Ltd
Wright Medical Australia
Zimmer Biomet

**Non-Members**

ResMed Pty Ltd

Draeger Australia Pty Ltd

GE Healthcare Australia Pty Limited

Philips Healthcare Australia

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

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

[Australian Business Mobiles \(NSW\) Pty Ltd](#)[Whiteley Corporation Pty Ltd](#)



[Mo Milling Pty Ltd](#)

[Multigate Medical Products Pty Ltd](#)

[Mun Australia Pty Limited](#)

[Australian Safety Wholesalers Pty Ltd](#)

[iSmile Group](#)

[Vapotherm Inc](#)

#### **New MTAA Members or Non-Members**

MTAA anticipates that the list of MTAA Members and Non-Members may be expanded and new MTAA Members or Non-Members may be added as the Federal Government's response to the crisis evolves and information relating to new medical equipment or products are required.

MTAA will notify the ACCC of any new MTAA Members or Non-Members to be covered by the terms of the authorisation.