Medicines Australia COVID-19 Response: *Interim authorisation rules for discussions and information sharing between Medicines Australia Members and GBMA Members*

1. Purpose

Medicines Australia sought urgent authorisation for the MA/GBMA Working Group to implement a coordinated strategy in relation to the supply of:

- prescription-only medicines that are critical to patient health, including medicines used to treat patients suffering from the symptoms of Covid-19 (**Critical Medicines**);
- devices or services that are supplied or administered with Critical Medicines, and therefore essential to the efficacy and proper administration of Critical Medicines (**Critical Devices**)

and to address shortages in the supply of Critical Medicines and Critical Devices that arise as a result of COVID-19.

On 3 April 2020, the ACCC granted to Medicines Australia (**MA**) interim authorisation to permit:

- Medicines Australia and any of its members (**MA Members**); and
- the Generic Biosimilar Medicines Association (**GBMA**) and any of its members (**GBMA Members**),

(together, the **MA/GBMA Working Group**)

And potential future members of the **MA/GBMA Working Group**, namely:

- the National Pharmaceutical Services Association (**NPSA**) and its members; and
- other persons whose identity will be notified to the ACCC, being:
    - new MA members;
    - persons who perform a significant role in the continued delivery of essential medicines and related supplies to the Australian community

to make and give effect to arrangements that implement this coordinated strategy.

A potential new member of the MA/GBMA working group seeking to participate in the authorised conduct must notify either the Medicines Australia or GBMA secretariat in writing which will then be notified to the ACCC.

Without this interim authorisation, conduct of this nature between competitors may be in breach of the *Competition and Consumer Act 2010* (Cth) (**Act**).

This document specifies rules to help you understand what is permitted when engaging with any other member of the MA/GBMA Working Group (**Permitted Activities**), and where legal advice is required **before** proceeding, to ensure there is no breach of the Act.[1]

Conduct outside the scope of the ACCC interim authorisation may be in breach of the Act.

Interim authorisation will be in place until final authorisation is granted. Authorisation has been sought for 6 months from the date when final authorisation is granted.

[1] Outside the scope of the interim authorisation, the Act and overall regulatory framework for the supply of prescription medicines continues to apply notwithstanding that the Minister has asked MA for assistance in supporting the continued supply of critical medicines during the COVID-19 pandemic.

The ACCC decision to grant interim authorisation and other relevant documents can be found at: https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/medicines-australia-0

If you have any questions, including whether any matter can be discussed or agreed between members of the MA/GBMA Working Group, please speak to Medicines Australia CEO, Elizabeth de Somer.

2. Permitted Activities

IMPORTANT: Interim authorisation does not apply to any conduct relating to non-critical medicines or for arrangements that do not relate to supply shortages in the supply of Critical Medicines or Critical Devices that arise as a result of COVID-19.

The activities which are permitted by the interim authorisation are specified in paragraphs 3, 10 and 11 of the ACCC decision to grant interim authorisation. Members of the MA/GBMA Working Group are permitted to engage in the following activities with one another facilitate the supply of Critical Medicines and Critical Devices. This includes, in consultation with the Federal Government and/or Federal Government Agencies such as the Therapeutic Goods Administration **(Permitted Activities)**:

✓ Sharing information regarding:

- availability of stock and inventory levels;
- likely quantities that can be obtained through existing supply channels;
- new sources of supply and potential quantities; and
- opportunities to increase domestic manufacturing,

for Critical Medicines and Critical Devices.

✓ Coordinating and allocating the fulfilment of orders and supply requests for Critical Medicines and Critical Devices between MA/GBMA Working Group members as suppliers.

✓ Prioritising certain requests for supply for Critical Medicines and Critical Devices as nominated by the Federal Government, State and Territory Governments agency, and relevant health authorities.

✓ Working together to respond to tenders or requests for supply (including sharing information or joint tenders) of Criticial Medicines and Critical Devices.

IMPORTANT: This Permitted Activity does **NOT** permit pricing to be shared or discussed between the MA/GBMA Working Group members.

✘ Do **not** engage in discussions or conduct involving **pricing or matters that are not Permitted Activities** without first getting **legal advice** (see section 6 below).

The Permitted Activities concern the supply of critical prescription medicines. In some cases, the critical prescription medicine will be used to treat patients suffering from the symptoms of COVID-19. In other cases, due to the increased demand, including because of the stockpiling behaviour, and global supply chain impacts, including export restrictions, border closures and freight capacity, the Permitted Activities will apply to potential shortages in critical prescription medicines that are not used directly to treat the symptoms of COVID-19. This reflects the wider impacts and stress on the health system attributable to the COVID-19 crisis. Further information and examples are provided in **Appendix A**.

IMPORTANT: Please let Elizabeth de Somer know if you are not a current Medicines Australia or GBMA member and wish to discuss supply issues as this needs to be notified to the ACCC.

A list of the current Medicines Australia and GBMA members covered by the interim authorisation is at **Appendix B**. Set out at **Appendix C** is a list of Frequently Asked Questions which you may have as a member of the MA/GBMA Working Group.

3. Practical Tip

➔ Clarify before acting/ doing if you are in doubt about whether:

- you can share certain information with other members of the MA/GBMA Working Group;
- your conduct is a Permitted Activity

4. Reporting to ACCC by the MA/GBMA Working Group

A condition of the interim authorisation is that the MA/GBMA Working Group must regularly update the ACCC regarding any material developments in relation to the Permitted Activities as the COVID-19 position evolves - including by:

- notifying the ACCC of:
  - material recommendations made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Permitted Activities;
  - material decisions or arrangements made by the MA/GBMA Working Group or members of the MA/GBMA Working Group which involve the Permitted Activities, including arrangements made to:
    - allocate supply between Working Group members;
    - prioritise requests for supply; or
    - respond to tenders or requests for supply;
  - any changes to the membership of the Working Group;
- providing to the ACCC within a reasonable timeframe all information reasonably requested by the ACCC in relation to the Permitted Activities; and
- meeting with the ACCC to provide regular updates in relation to the Permitted Activities, as agreed by the Applicants and the ACCC.

5. Conduct of MA/GBMA Working Group meetings

✓ Ensure an **agenda** is circulated in advance of all MA/GBMA Working Group meetings. Speak to Elizabeth de Somer if you are unsure whether a matter listed in the agenda should be discussed.

✓ Ensure that accurate **minutes** are taken at all MA/GBMA Working Group meetings and all Working Group Members in attendance are noted.

✓ Make it clear that discussions within the MA/GBMA Working Group about matters other than the Permitted Activities are merely discussions and that no arrangements or commitments to cooperate are made.

✓ Mark written documents "confidential and subject to legal advice" where they record matters that are not Permitted Activities that may require legal or regulatory advice before they can be implemented.

✓ If you have concerns about a topic that is raised at a MA/GBMA Working Group meeting, immediately state that discussion of that topic may give rise to legal risk and should be parked until legal advice can be obtained.

✘ Avoid discussing matters at MA/GBMA Working Group meetings that are not set out in the agenda.

✘ Do not record the implementation of matters outside the Permitted Activities as having been "agreed" until legal advice has been obtained on the implications of such an agreement.

✘ Do not encourage MA/GBMA Working Group members to contact one another outside the meetings to discuss non-Permitted Activities.

✘ Do not circulate information/documents to more people than necessary – only circulate to those people that need to know the information.

6. Other matters not covered by the Permitted Activities

✘ Do not proceed without legal advice before discussing or agreeing to implement any other measures or activities that are **not** a Permitted Activity as described above (and in Appendix A).

Failure to do so will give rise to risk including:

- **Cartel risk**, where some/all of the MA/GBMA Working Group members agree to act together in the following ways, rather than making their own independent decisions and competing as independent suppliers:
  - the fixing of any aspect of prices (e.g. discounts, credits etc); or
  - restrict or limit on the supply/output of goods or services e.g. non-critical medicines or non-prescription medications; or
  - allocating markets/territories/customers as between Working Group members; or
  - bid-rigging.
- **Concerted practices risk**, which is broadly defined and can capture sharing of information that would help one or more Working Group members to anticipate what other members will do and take steps to reduce competition.

Appendix A: Permitted Activities

Permitted Activity	Illustrative examples (non exhaustive)
a. **Supply chain**: communicating and sharing information with Working Group members as to: • available stock levels for critical medicines and related supplies; • identifying any shortage of critical medicines and related supplies; • how identified shortages in the supply of critical medicines may be resolved; • what quantities of critical medicines and related supplies are available through existing supply chains	As a result of stockpiling of medicines because of COVID-19, Working Group members or the Federal Government have identified a short supply of *olmesartan*. Working Group members may discuss whether they have available stock to meet the supply or whether it is necessary to discuss with the TGA where Working Group members do not foresee a resolution to the supply shortage.
b. **Government requests**: sharing information and communicating with Working Group members to respond to requests for supply of critical devices or services supplied or administered with a medicine, where there is an identified shortage	*Medicines:* The Federal Government requests that asthma spacers be made available as a priority to respond to COVID-19. MA/GBMA Working Group members may discuss how to meet the Federal Government's request. *Services:* MA/GBMA Working Group members may discuss how to meet a supply shortage for home infusion services for the treatment of cancer and other rare diseases, and notify that shortage to the Government.
c. **Government tenders:** Working Group members may work together to respond to tenders or tender requests for supply (including by sharing information on stock levels but **not** pricing) of products facing shortages as a result of COVID-19	The Federal or State/Territory government may request supply of a critical medicine that a single supplier is unable to meet, requiring MA/GBMA Working Group members to enter into discussions to source sufficient supply stock. Alternatively, State hospitals may request additional stock of critical medicines that a current supplier (awarded under tender) is unable to meet due to increased demand from COVID-19. MA/GBMA Working Group members (who may not have been the awarded the tender) may enter into discussions and arrangements to supplement the supply of the critical medicines to meet stock requirements.
d. **Supply chain logistics:** communicating and sharing information in relation to supply logistics regarding the above.	MA/GBMA Working Group members may need to discuss alternative supply arrangements where, for example, shipments of critical medicines have been interrupted as a result of COVID-19.

Appendix B: List of Medicines Australia and GBMA Members

Medicines Australia (MA) Members

- A. Menarini Australia Pty Ltd
- AbbVie Pty Ltd
- Amgen Australia Pty Ltd
- Astellas Pharma Australia Pty Ltd
- AstraZeneca Pty Ltd
- Bayer Australia Limited
- Biogen Australia Pty Ltd
- Boehringer Ingelheim Pty Ltd
- Bristol-Myers Squibb Australia Pty Ltd
- Celgene Pty Limited
- Eisai Australia
- Eli Lilly Australia Pty Ltd
- Gilead Sciences Pty Ltd
- GlaxoSmithKline Australia Pty Ltd
- Ipsen Pty Ltd
- Janssen Pty Ltd
- Merck Healthcare Pty Ltd
- Merck Sharp & Dohme (Australia) Pty Ltd
- Novartis Pharmaceuticals
- Novo Nordisk Pharmaceuticals Pty Ltd-Australia
- Pfizer Australia Pty Ltd
- Roche Products Pty Limited
- Sanofi
- Shire Australia Pty Ltd
- Takeda Pharmaceuticals Australia Pty Ltd
- UCB Australia Pty Ltd
- Vifor Pharma
- Besins Healthcare Australia Pty Ltd
- Norgine Pty Ltd
- FIT-BioCeuticals Ltd
- Medlab Clinical Limited
- Direct Cold (A Direct Couriers Company)
- Commercial Eyes Pty Ltd
- Covance Pty Ltd
- Biointelect
- Hahn Healthcare Pty Ltd
- IQnovate (Farmaforce, Clinical Research Corporation)
- Princeton Health
- Prospection Pty Ltd
- IQVIA
- Symbion Pty Ltd

GBMA Members

- Arrotex Pharmaceuticals Pty Ltd
- Celltrion Healthcare Australia Pty Ltd
- Fresenius Kabi Australia Pty Limited
- Juno Pharmaceuticals Pty Ltd
- Mylan Australia
- Sandoz Pty Ltd.
- Southern Cross Pharma Pty Ltd

GBMA Associate Members

- Commercial Eyes Pty Ltd
- IQVIA
- Sinapse Pty Ltd

New Working Group members

- Medicines Australia anticipates that the list of Working Group members may be expanded to add non-members and new MA Members, GBMA Members or, potentially, NPSA Members in response to the crisis as it evolves and information relating to new medicines and suppliers are required.

Appendix C: Frequently Asked Questions

What conduct is authorised?

The ACCC's interim authorisation permits Medicines Australia and its members, and GBMA and its members, to implement a coordinated strategy to address any shortages in the supply of Critical Medicines and Critical Devices including (but is not limited to):

(a) sharing information regarding:

(i) available stock and inventory levels;

(ii) likely quantities that can be obtained through existing supply channels;

(iii) new sources of supply and potential quantities; and

(iv) opportunities to increase domestic manufacturing

(b) coordinating and allocating the fulfilment of orders and supply requests, as nominated by the Federal, State and Territory Governments and relevant health authorities;

(c) prioritising certain requests for supply, as nominated by the Federal, State and Territory Governments and relevant health authorities;

(d) working together to response to tenders or requests for supply (including sharing information or joint tenders).

For how long does the interim authorisation apply?

The interim authorisation applies until it is revoked or the ACCC grants final authorisation for the conduct. Final authorisation is expected by September 2020. Medicines Australia has sought for final authorisation to apply for 6 months from the date of final authorisation.

What are "Critical Medicines"?

The ACCC interim authorisation defines "Critical Medicines" to be prescription-only medicines that are critical to patient health, including medicines used to treat patients suffering from the symptoms of COVID-19.

While prescription medicines used to treat the symptoms of COVID-19 are included in this definition, it also includes other prescription medicines that are critical to patient health, that may face supply shortages as a result of COVID-19 (but which are not directly related to the treatment of COVID-19). An example of a medicine that may be included in this definition and not used to directly treat the symptoms of COVID-19 are antihypertensives.

What are "Critical Devices"?

"Critical Devices" are devices or services that are supplied or administered with Critical Medicines and therefore essential to the efficacy and proper administration of Critical Medicines.

As for Critical Medicines, Critical Devices are devices or services that may face supply shortages as a result of COVID-19.

In order to permissibly engage in the conduct that is within the scope of the authorisation, it is sufficient that there is a shortage of either a Critical Medicine or a Critical Device. There does not need to be both.

Are the Permitted Activities limited to activities directly related to the COVID-19 crisis?

No, the authorisation is not specifically limited to treatments for the symptoms of COVID-19 and extends to Critical Medicines and Critical Devices where there is a supply shortage as a result of COVID-19 (for example, interruptions to supply logistics, stockpiling).

I am a member of Medicines Australia or GBMA. Do I have to participate in the Permitted Activities?

No. Participation in conduct within the scope of the interim authorisation is not compulsory, even if you are a member listed in Medicines Australia's application to the ACCC. If you do not wish to participate in any conduct within the scope of the authorisation, please let Medicines Australia know.

What do I need approval for?

You should notify Medicines Australia that you intend to engage in, or are requested to engage in, any of the conduct that falls within the Permitted Activities. You should not engage in any coordinated conduct with another supplier that does not fall within the Permitted Activities, or falls within the Permitted Activities, but has not first been notified Medicines Australia.

Who should I contact before engaging in a Permitted Activity?

You should contact Medicines Australia (Elizabeth de Somer at edesomer@medaus.com.au).

Does the TGA need to be involved?

Generally the TGA, or another Federal, State or Territory Government or health authority will be involved either because:

(a) the Government or health authority has requested you and other members of the MA/GBMA Working Group to engage in the conduct (for example, issued a request for information, or notified you or another MA/GBMA Working Group member of a potential shortage of a Critical Medicine or a Critical Device); or

(b) you or another MA/GBMA Working Group member identify a supply issue concerning a Critical Medicine and/or Critical Device and, through MA, notify the relevant Government agency or health authority.

What is the process for adding members to the MA/GBMA Working Group?

Should you become aware that another supplier wishes to become a member of the MA/GBMA Working Group, please notify Medicines Australia, who will notify the ACCC as it is required to do under the reporting condition (see below). This notification should be made ***before*** the supplier participates in any discussions with an MA/GBMA member or meeting of the MA/GBMA Working Group because even though pre-notification is not a condition of the authorisation, Medicines Australia has committed to do so.

What needs to be reported to the ACCC?

The ACCC interim authorisation requires Medicines Australia to regularly:

(a) notify the ACCC of material recommendations made to the Federal Government or Federal Government Agency by the MA/GBMA Working Group in relation to the Permitted Activities;

(b) notify the ACCC on material decisions or arrangements made by the MA/GBMA Working Group or its members which involve the Permitted Activities;

(c) notify the ACCC of any changes to the MA/GBMA Working Group membership, including new members;

(d) provide all information reasonably requested by the ACCC, within a reasonable timeframe; and

(e) meet with the ACCC to provide regular updates in relation to the Proposed Conduct by MA/GBMA members.

The above requirements do not expressly specify how often Medicines Australia needs to report to the ACCC; this will depend on the developments as they arise in dealing with COVID-19.

Additionally, the interim authorisation does not define what is "material" and Medicines Australia will need to decide what is material in the circumstances. In order to do so, Medicines Australia requires MA/GBMA members to notify it of any proposed conduct that falls within the Permitted Activities between MA/GBMA Working Group members.

How often is reporting required to the ACCC?

As often as is necessary under the terms of the reporting conditions described above.

Who reports to the ACCC?

Medicines Australia is required to report to the ACCC in accordance with the reporting requirements under the ACCC interim authorisation. MA/GBMA members should provide Medicines Australia with information promptly and as is necessary for it to do so in a timely manner.