Medicines Australia –
Application for authorisation AA1000486
Interim authorisation decision
3 April 2020

Decision

1. The Australian Competition and Consumer Commission (the **ACCC**) has granted conditional interim authorisation in respect of the application for authorisation AA1000486 lodged by the Medicines Australia (**MA**) on 27 March 2020.
2. MA has applied for authorisation on behalf of itself and its members, and the Generic and Biosimilar Medicines Association (**GBMA**) and its members.
3. The ACCC has granted conditional interim authorisation for the conduct described at paragraphs 10 and 11 below. Interim authorisation commences immediately and remains in place until it is revoked or the date the ACCC's final determination comes into effect.

Background

4. MA represents the discovery-driven pharmaceutical industry in Australia.
5. The GBMA is the national association representing generic and biosimilar medicine suppliers in Australia.
6. MA and GBMA are assisting the Department of Health to identify potential issues relating to the supply of essential medicines and associated supplies, including those necessary for the treatment of COVID-19 patients, and to ensure measures are in place to mitigate any medicines shortages or supply chain issues in the near future.

The application for authorisation

7. MA seeks authorisation on behalf of:
   (a) itself and its members; and
   (b) the GBMA and its members,

   (together, the **MA/GBMA Working Group**) to engage in the proposed conduct described below.
8. MA also seeks authorisation in respect of all potential future members of the MA/GBMA Working Group, namely:
   (a) the National Pharmaceutical Services Association (**NPSA**) and its members; and
   (b) 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,
9. MA submits that in order to respond to the Federal Government's requests, coordination among the MA/GBMA Working Group will be necessary to identify current

stock levels, likely quantities that can be obtained through existing supply channels, new sources of supply and potential quantities, as well as opportunities to increase domestic manufacturing and sharing of resources between (some or all) members of the MA/GBMA Working Group.

The Proposed Conduct

10. MA seeks urgent authorisation for the MA/GBMA Working Group to implement a coordinated strategy in relation to the supply of:

    (1) prescription-only medicines that are critical to patient health, including medicines used to treat patients suffering from the symptoms of Covid-19 (**Critical Medicines**)

    (2) 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**)

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

11. This includes, in consultation with the Federal Government and/or Federal Government Agencies such as the Therapeutic Goods Administration:

    (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,

        for Critical Medicines and Critical Devices,

    (b) coordinating and allocating the fulfilment of orders and supply requests for Critical Medicines and Critical Devices between MA/GBMA Working Group members as suppliers;

    (c) prioritising certain requests for supply for Critical Medicines and Critical Devices 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) of Critical Medicines and Critical Devices (the **Proposed Conduct**).

12. MA has clarified that the Proposed Conduct contemplated by paragraph 11(d) is conduct:

    (a) concerning tenders let, or to be let, by Federal or State Governments; and

    (b) will not encompass making or giving effect to agreements and arrangements, or exchanging information between MA/GBMA Working Group members on the pricing aspects of such tenders.

13. MA seeks authorisation for an initial period of six months from the date of final authorisation, but notes that the period may need to be extended, given the difficulties in predicting the duration and extent of the COVID-19 pandemic.

The authorisation process

14. 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.

15. The power conferred upon the ACCC to authorise conduct is discretionary. In exercising that discretion, the ACCC may have regard to considerations relevant to the objectives of the Act.

16. The ACCC may specify conditions in an authorisation. The legal protection provided by an authorisation does not apply if any conditions are not complied with.

Interim authorisation

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

18. MA requests urgent interim authorisation so that MA/GBMA Working Group members can start working together to:

    - address supply shortages for critical medicines and associated supplies, and
    - where necessary, provide information and advice to the Federal, State and Territory Governments and relevant health agencies in relation to supply of essential medicines and associated supplies, including areas of current or anticipated shortage and supply constraints.

19. MA submits that the Australian health system is already suffering from a shortage of essential medicines and supplies, which may hamper Australia's response to this public health crisis.

Consultation

20. The ACCC has not conducted a public consultation process in respect of the request for interim authorisation. This is due to the urgent need to ensure the continued supply of essential medicines and associated supplies, including those needed for the treatment of COVID-19 to Australians, and the compelling nature of the public benefits likely to result from the request for interim authorisation.

21. The ACCC will conduct a public consultation process on the substantive application for authorisation and will further examine the public benefits and detriments likely to result from the Proposed Conduct during that process. Details regarding how to make a submission will be available on the ACCC's authorisations public register.

Granting of conditional authorisation

22. Interim authorisation is granted for the Proposed Conduct[1] subject to the following condition:

    The Applicants will regularly update the ACCC regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves, including by:

    1. notifying the ACCC of:
        a. material recommendations made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Proposed Conduct;

[1] As clarified by MA that the Proposed Conduct contemplated by paragraph 11(d) is conduct (a) concerning tenders let, or to be let, by Federal or State Governments and (b) will not encompass making or giving effect to agreements and arrangements, or exchanging information between MA/GBMA Working Group members on the pricing aspects of such tenders.

b. material decisions or arrangements made by the MA/GBMA Working Group or members of the MA/GBMA Working Group which involve the Proposed Conduct, including arrangements made to:

i. allocate supply between MA/GBMA Working Group members;

ii. prioritise requests for supply; or

iii. respond to tenders or requests for supply;

c. any changes to the membership of the MA/GBMA Working Group and the identity of any new members;

2. providing to the ACCC, within a reasonable timeframe, all information reasonably requested by the ACCC in relation to the Proposed Conduct; and

3. meeting with the ACCC to provide regular updates in relation to the Proposed Conduct, as agreed by the Applicants and the ACCC.

Reasons for decision

23. In granting interim authorisation, the ACCC recognises the urgency of the request for interim authorisation in light of the significant demands being placed on the Australian health system as a result of the COVID-19 pandemic.

24. In addition, the ACCC considers that:

- It is unlikely that interim authorisation will significantly weaken competition in any market in the long run. In particular:
  - The Proposed Conduct is a temporary measure in response to a national crisis.
  - The Proposed Conduct, and interim authorisation, only apply to arrangements and conduct for the purposes of implementing a coordinated strategy in relation to the supply of Critical Medicines and Critical Devices in the circumstances of the current COVID-19 pandemic.
  - The Proposed Conduct contemplated by paragraph 11(d) above is conduct (a) concerning tenders let, or to be let, by Federal or State Governments and (b) will not encompass making or giving effect to agreements and arrangements, or exchanging information between MA/GBMA Working Group members on the pricing aspects of such tenders..
  - The Proposed Conduct is not compulsory and any participant can opt out of any information sharing arrangements or other authorised conduct.
  - Pursuant to the condition outlined above, MA will notify the ACCC regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves, including any material recommendations made by the MA/GBMA Working Group to the Federal Government and material decisions or arrangements it makes.
  - The Proposed Conduct will be undertaken in the context of broader coordination and communication by the MA/GBMA Working Group with relevant Government and regulatory bodies, including the Therapeutic Goods Administration.
  - 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 any persons, including relevant Government and regulatory bodies, have concerns with the way the Applicants are dealing with them during the period of interim authorisation, they are encouraged to advise the ACCC.

- There are likely to be significant public benefits of permitting the MA/GBMA Working Group to engage in the Proposed Conduct in the current unprecedented circumstances, including enabling MA/GBMA Working Group members to:
    - coordinate discussions within the medicines supply chain to develop and implement strategies to ensure the continued supply of essential medicines and supplies to Australians;
    - provide more effective advice to governments and relevant health agencies regarding the supply of essential medicines and associated supplies including by identifying and addressing supply shortages and constraints; and
    - maximising the efficient use of supply channels in this time of peak demand.

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.
26. 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.