17 July 2020

Mr Simon Bell
Assistant Director - Adjudication Branch
Australian Competition and Consumer Commission
Level 17, 2 Lonsdale Street
Melbourne VIC 3000

Dear Mr Bell

Application for authorisation AA1000486 - Medicines Australia - submission in response to ACCC's Draft Determination

1. We refer to your email to Clayton Utz dated 26 June 2020 attaching the ACCC's Draft Determination in respect of Medicines Australia's (**MA**) application for authorisation and inviting MA to respond to the Draft Determination.

2. MA appreciates the support of the interested parties who have engaged in the ACCC's public consultation to date in relation to the interim authorisation granted to MA on 3 April 2020 (**Interim Authorisation**), and welcomes the opportunity to now respond to the ACCC's Draft Determination.

3. MA supports the terms of the Draft Determination proposing to grant conditional authorisation to current and future members of the MA/GBMA Working Group, to implement a coordinated strategy in relation to the supply of Critical Medicines and Devices in response to the COVID-19 pandemic (**Conditional Authorisation**).

4. MA recognises that Conditional Authorisation to permit the MA/GBMA Working Group to continue to engage in the Proposed Conduct as necessary is made in extraordinary times and only where it is for the sole purpose of ensuring continuity of supply of Critical Medicines and Devices in response to potential shortages that may arise as a result of the COVID-19 pandemic.

Operation of the Interim Authorisation

5. To date, the Interim Authorisation has been operating in precisely this manner. Pursuant to the Interim Authorisation and with full transparency front of mind, MA has been keeping the ACCC well-informed of meetings of the MA/GBMA Working Group and the Therapeutic Goods Administration (**TGA**).

6. MA has been careful to ensure that MA/GBMA Working Group members recognise the limited scope of the Proposed Conduct. MA has responsibly implemented safeguards to ensure that Working Group meetings under the Interim Authorisation have remained within the boundaries of the Proposed Conduct (for example, by the attendance of external legal counsel). Ensuring that MA/GBMA Working Group participants do not exchange information in relation to any aspect of cost or pricing continues to be a primary focus for MA.

7. Although there was a period of heightened demand for Critical Medicines and Devices in the initial period following the grant of Interim Authorisation, to date MA/GBMA Working Group

members have been able to unilaterally address any challenges to the supply of Critical Medicines and Devices, and have not needed to engage in any coordinated conduct pursuant to the interim authorisation. This remains the preference of MA/GBMA Working Group members and any discussion under the Conditional Authorisation will continue to preference unilateral action until it becomes necessary to engage in any coordinated conduct.

8. However, recent events in Australia illustrate that COVID-19 infections remain present and, in some areas, may be accelerating. While there was some success in flattening the curve since the Interim Authorisation was granted, the recent increases of infections in Victoria and NSW demonstrate the ever-present risks of resurging infection and increased community transmission. . The threat of a second wave and further waves is credible and some State and Territory purchasing authorities are continuing to place further orders to support their stock of Critical Medicines and Devices. It remains critical through the Conditional Authorisation that the medicines industry is able to ensure continuity of supply and respond effectively and promptly to any further potential shortages.

Practical considerations

9. The pressure on the supply of Critical Medicines and Devices that may be caused by an increasing prevalence of infection rates in Australia is further compounded by the responses to the pandemic overseas, in particular in those countries where manufacturing facilities are located. MA (and the TGA) is aware that some supply chains may prioritise the distribution of Critical Medicines and Devices to countries where there are much higher infection and mortality rates and subsequently more critical needs for immediate use of those medicines; as compared to countries that are seeking to reinforce their stockpile of Critical Medicines and Devices in preparation of a potential outbreak. The uncertain and dynamic situation both locally and globally means that suppliers need to react quickly to local and global changes. In MA's view, enabling the conduct permitted under the Conditional Authorisation to take place is necessary and appropriate to assist suppliers to respond quickly to these changing demands and challenges, in order to ensure the continued supply of Critical Medicines and Devices in Australia.

10. The ability for an MA/GBMA Working Group member to share supply information provides alternative suppliers of a Critical Medicine or Device to obtain an early warning of a potential supply shortage and investigate whether additional stock can be sourced. Early signals of a potential shortage are vital, as suppliers typically have a 2 to 4 month lead time to obtain additional stock. This information exchange between suppliers is supplemented by information provided by the Department of Health, in particular the TGA, which is assessing current stock levels and potential future demand from State and Territories to assist in the development of forecasting models that address a variety of increased-demand scenarios. As a result, suppliers have an enhanced ability to react to potential shortages and take steps to ensure that the supply of Critical Medicines and Devices continues.

Role of the TGA

11. Since the Interim Authorisation was granted by the ACCC, the occurrence of, and conduct during, the discussions between MA/GBMA Working Group members and the TGA has evolved with the TGA taking a more central role in coordinating the discussions and

identifying the issues to be addressed. This is a result of the TGA's continued engagement with State and Territory purchasing authorities in the development of modelling that allows all relevant parties to better predict supply requirements in various circumstances where demand for Critical Medicines and Devices increases.

12. MA supports the TGA in this role and considers that this form of arrangement under the Conditional Authorisation further mitigates the risk that discussions would move outside the scope of the Proposed Conduct.

13. Additionally, any material decisions or actions arising from those discussions are at the request, or with the express involvement and endorsement, of the TGA. MA remains confident that the involvement of the TGA as well as other relevant Federal Government bodies (including the Department of Health) will encourage fair supply without any undue preferencing of MA/GBMA customers, whilst at the same time balancing any particular areas of public need.

Reporting Condition

14. MA supports the ACCC's proposed reporting condition set out in the Conditional Authorisation. MA considers that any discussions held pursuant to the Conditional Authorisation must remain transparent and MA intends to continue to actively engage with the ACCC through regular reporting even where the reporting condition is not satisfied. As necessary, MA is also willing to meet with the ACCC to provide regular updates in relation to the Proposed Conduct.

Term of Conditional Authorisation

15. The ACCC proposes the Conditional Authorisation to operate until 27 March 2021 (which is six months from the date of the Final Determination).

16. Due to the unpredictable nature of the COVID-19 pandemic in Australia and overseas, the period within which MA/GBMA Working Group members may need to engage in discussions about the supply of Critical Medicines and Devices is unknown and will likely need to be extended beyond 27 March 2021.

17. While MA/GBMA Working Group members are hopeful that the COVID-19 pandemic does not continue to threaten the supply of Critical Medicines and Devices when the Conditional Authorisation is set to expire, recent events, including those overseas, raise the real prospect that challenges to the supply of Critical Medicines and Devices will persist beyond 27 March 2021.

18. MA would like to avoid the need to apply for revocation and substitution of the Conditional Authorisation prior to the expiry of the Conditional Authorisation (or at least postpone for six months the need to make such an application promptly after Conditional Authorisation). For reasons outlined below, MA is of the view that it would be in the public interest, and requests, that the Conditional Authorisation be extended for a further period of 6 months until 27 August 2021:

    (a) the Australian community will not likely be safe from outbreaks of COVID-19 infections until a vaccine is developed, manufactured, and widely provided throughout the globe and domestically and/or treatments are successfully identified to manage the severity of infections;

(b) even if a vaccine is discovered later this year or early next, its manufacture and distribution to the point of substantially decreasing risks to the most vulnerable will not likely occur until beyond 27 March 2021 and the long term efficacy of any such vaccine(s) will not be known for some time;

(c) the recent resurgence of the COVID-19 in certain locations in populous states indicates that the pandemic is unpredictable and requires rapid and flexible responses from health authorities and the suppliers of Critical Medicines and Devices;

(d) there can a substantial lead time for ordering and fulfilment of Critical Medicines and Devices which requires lengthy forward planning, and it is possible that border closures will impact freight movements; and

(e) manufacture of certain Critical Medicines and Devices occurs overseas and the concerning trajectory and prevalence of COVID-19 in certain countries carries the risk of diversion to those markets. This may result in Australia being affected even if the disease is controlled domestically with an associated continued need to co-ordinate supplies.

19. Should a vaccine and successful treatment(s) for COVID-19 become available in sufficient quantities in Australia before 27 August 2021, MA will contact the ACCC about revocation of the Conditional Authorisation prior to that date.

20. MA welcomes any further feedback from interested parties or the ACCC in respect of the Proposed Conduct and this submission.

Please do not hesitate to contact us for further information.

Yours sincerely,

Chief Executive Officer

Medicines Australia