10 June 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 - Medicines Australia - further response to submissions from ACCC's public consultation process

1. We refer to your email to Clayton Utz dated 2 June 2020 informing Medicines Australia (**MA**) of the completion of the ACCC's public consultation in relation to the interim authorisation granted to MA on 3 April 2020 (**Interim Authorisation**) and its receipt of submissions arising from that process.

2. MA appreciates the further support of those interested parties that have made submissions to the ACCC, and is pleased to take this opportunity to provide a further submission.

3. MA considers that the Proposed Conduct engaged in by certain members of the MA/GBMA Working Group under the terms of the Interim Authorisation is functioning as intended during the unprecedented public health crisis to address any potential shortages in the supply of Critical Medicines and Devices, that have been identified by the TGA or the Department of Health (**DoH**) or otherwise by the relevant suppliers, MA or GBMA.

4. Following identification of a potential supply shortage of a Critical Medicine or Device, only those suppliers of the Critical Medicine or Device have been invited to participate in discussions with the TGA/DoH and members of the MA and GBMA executive. This has been strictly observed to date, and MA has provided the ACCC and the public with transparency by means of weekly reports where a meeting has occurred (or has notified where no meeting has occurred). This is in recognition of the highly unusual nature of the potential co-ordination among suppliers of Critical Medicines and Devices and the need to provide confidence to stakeholders that the collaboration, where necessary for it to occur in the context of the authorisation, is conducted within the strict parameters set by and for the purpose described in the application for authorisation.

5. Where a discussion has occurred, its sole purpose has been to seek to identify the source or cause of the potential supply shortage and to establish whether future conduct between the relevant parties to the discussion requires coordination to ensure that any supply shortage of the Critical Medicine or Device is averted or managed appropriately in the public interest.

6. The discussions which have occurred concern only supply issues (including for example, stockpile orders and supply logistics). No aspect of price or cost information of any of the parties has been discussed. All meetings have also been attended by a competition law observer.

7. To date, the potential supply shortages identified, and resulting discussions, have involved information sharing of a kind which might raise concerns under Part IV in the absence of Interim Authorisation, but have not required the relevant parties to engage in any coordinated conduct to resolve those potential supply issues, and it has been sufficient that the relevant parties have been able to unilaterally undertake certain actions to avoid or resolve those issues.

8. MA understands that many potential supply issues have arisen from the misinformation within a supply chain and, in most cases, the identified issues have been resolved through appropriate communication and accurate information being obtained and provided to stakeholders.

9. MA is pleased that the interim Authorisation has allowed efficient and necessary engagement between the parties to identify the relevant supply issues and deploy appropriate actions to resolve those issues. There is no doubt that absent the rapid ability to have such coordinated communications and information sharing with Government stakeholders and among members, the response to potential shortages would not have been as effective.

10. To date, no material decisions or actions that would be notifiable to the ACCC under the terms of the reporting condition in the Interim Authorisation have needed to be made (although, as noted above, MA has nevertheless provided to the ACCC weekly reports of activities in accordance with the Interim Authorisation).

11. Although restrictions are starting to ease, like the Governments of Australia and the public, MA and its members are cautious that the challenges arising from COVID-19 are not over. MA recognises that further potential supply shortages of Critical Medicines and Devices may arise as a result of further outbreaks of COVID-19 as restrictions are eased in each State and Territory and travel resumes in the coming months (thereby increasing the potential for the virus to spread again and a possible second wave). This is particularly so as Australia moves into the winter months ahead.

12. While the discussions to date that have taken place under the Interim Authorisation have not required coordinated conduct or any material decisions or actions, MA considers there is a need for the mechanisms in place under the Interim Authorisation to remain in place for a period of 6 months after the final determination is issued, as the threat of COVID-19 persists and the need for information sharing and communications continues. This is because the supply chain will continue to be impacted by events outside Australia and those effects continue to be felt notwithstanding the very positive results of the public health protection measures to date in Australia and the ordering and supply of Critical Medicines and Devices can occur many months in advance of supply to a patient.

13. MA welcomes further engagement with the ACCC if necessary to enable the Proposed Conduct to continue to ensure the continued supply of Critical Medicines and Devices arising from COVID-19.

Please do not hesitate to contact us for further information.

Yours sincerely,

Chief Executive Officer

Medicines Australia