

Mr Darrell Channing  
Director  
Merger and Authorisation Review  
Australian Competition and Consumer Commission  
23 Marcus Clarke Street  
Canberra 2601

1 April 2020

Dear Mr Channing

**Medicines Australia - urgent application for interim authorisation**

The purpose of this letter is to provide further information concerning the urgent application lodged on behalf of Medicines Australia (**MA**) on 27 March 2020 seeking interim authorisation for conduct in relation to the supply of essential medicines and related supplies in response to the current COVID-19 crisis (**Application**).

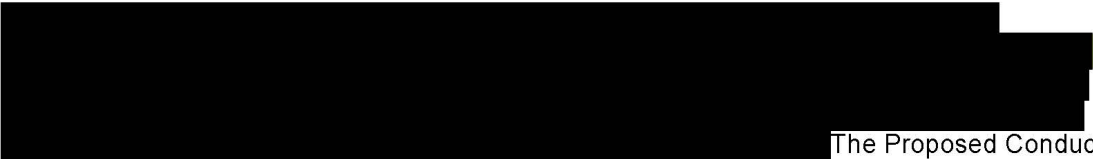
**The Proposed Conduct**


1. The Application defines Proposed Conduct to be "to implement a coordinated strategy in relation to the supply of essential medicines and related supplies in response to the current COVID-19 crisis" (page 2 (cover letter) of Application).
2. The conduct described in sub-paragraphs 13(a) to (d) comprises examples of the Proposed Conduct and is not intended to provide an exhaustive list or to limit the Proposed Conduct as more broadly defined. Due to the rapidly evolving nature of the current COVID-19 crisis, MA is unable, at this time, to more specifically characterise the conduct that may be the subject of the Application. However, MA is able to provide the further information below.

3. [Redacted]

4. MA anticipates that the Proposed Conduct will largely be coordinated with the Federal Government (e.g. through the TGA or related agencies) which is responsible for identifying a list of critical prescription medications which may suffer from shortages. MA expects that the Proposed Conduct will either be:
  - (a) led by the TGA who is responsible for identifying prescription medications shortages that may have a critical impact on patient health, for example, by issuing requests to suppliers who will enter into discussions with the TGA in an effort to rectify those shortages; or
  - (b) led by suppliers (that is, members of MA or GBMA) who, if they identify a critical prescription medications shortage, will collaborate with and provide information to the TGA prior to entering into the Proposed Conduct in an effort to rectify the shortage and for Government planning purposes.
5. In each case, the Proposed Conduct will be specific to a certain specified prescription medications identified by the Government as critical and, as a result, will involve only those suppliers from the subset of MA and GBMA members that are relevant to the supply of that medication (or those medications) on a "needs" basis, and utilise existing communication mechanisms established by the Federal Government (e.g. by the TGA).

#### Goods covered by the Proposed Conduct

6. The Proposed Conduct concerns the supply of critical prescription medications. In some cases, the critical medicine that will be the subject of the Proposed Conduct will be used to treat patients suffering from the symptoms of COVID-19.
7. In other cases, due to the increased demand, including because of the stockpiling behaviour (which in some cases, has seen patient demand increase by up to 300% above normal levels of demand), potential shortages in critical prescription medications that are not used directly to treat the symptoms of COVID-19 will be the subject of the Proposed Conduct. This reflects the wider impacts and stress on the health system attributable to the COVID-19 crisis.
8. 

The Proposed Conduct seeks to ensure that in the event of a shortage of a critical prescription medication, relevant parties are able to identify alternative sources of the medication or alternative clinical treatments, to ensure that poor patient outcomes through medicine shortages are not observed.
9. The Proposed Conduct also seeks to include devices or services that are supplied or administered with the medication, and therefore, essential to the efficacy and proper administration of those critical medicines. 

10. In all cases, MA confirms that:
  - (a) the goods covered by the Proposed Conduct are critical to patient health; and
  - (b) the Proposed Conduct seeks to address shortages in the supply of critical prescription-only medications that arise as a result of COVID-19.
11. Interim authorisation is not sought for any conduct relating to non-essential medicines or for arrangements that do not relate to supply shortages resulting from the COVID-19 crisis.

#### **Categories of conduct and notification process**

12. MA presently anticipates that the primary conduct likely to be the subject of the Proposed Conduct is the exchange of information described in paragraph 13(a) of the Application.
13. However, as a result of the rapid and continually evolving nature of the COVID-19 crisis, MA considers that the conduct described under paragraphs 13(b) to (d) is likely to also arise. MA confirms however, that in each case, the conduct described under paragraphs 13(a) to (d) will only be engaged in after close communication with, and involvement by, the Federal Government (through the TGA and related agencies). At present there is frequent communication with the TGA concerning the evolving COVID-19 situation and the availability of critical medicines to patients.

#### **Possible Condition**

14. MA is aware of the interim authorisation granted by the ACCC to the National Pharmaceutical Services Association (**NPSA**) and, in particular, the condition set out at paragraph 21 of the ACCC's decision of 31 March 2020, which requires the NPSA to regularly update the ACCC regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves including in respect of certain specified events.
15. MA would not object to the grant of interim authorisation to MA in respect of the Proposed Conduct, subject to a similar condition to update the ACCC (in some cases, on a confidential basis) regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves including:
  - (a) any material recommendations made to the Federal Government by the Working Group;
  - (b) key operational and supply arrangements and material conduct consistent with any Federal Government direction or request; and
  - (c) any changes to the Working Group.
16. MA appreciates the ACCC's recognition of the urgency in the current circumstances and acknowledges its desire to have appropriate oversight of the Proposed Conduct. MA considers that the proposed condition as outlined above is appropriate to keep the ACCC informed of relevant matters without unduly diverting scarce resources from the Proposed Conduct to be undertaken in the national interest.

Mr Darrell Channing, Merger and Authorisation Review

1 April 2020

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Yours sincerely

**Bruce Lloyd, Partner**



**Mihkel Wilding, Special Counsel**



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