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**From:** [REDACTED]  
**Sent:** Friday, 1 October 2021 2:38 PM  
**To:** Exemptions; Haly, Anthony; Mitchell, Sophie; Bell, Simon  
**Cc:** [REDACTED]  
**Subject:** Medicines Australia – ACCC Authorisation AA1000486 – fortnightly report 18 September 2021 to 1 October 2021

Dear ACCC,

We refer to the ACCC Authorisation **AA1000486** granted to Medicines Australia on 24 September 2020 and the condition of the Authorisation under paragraph 5.12 of the Final Determination that requires Medicines Australia to report to the ACCC on a fortnightly basis on any meetings, discussions, developments and decisions in relation to the Proposed Conduct (as defined under paragraphs 1.8-1.10 of the Final Determination).

In the period of 18 September 2021 to 1 October 2021, the TGA convened a meeting on 29 September 2021 with sponsors of [REDACTED] to facilitate discussions between the TGA and sponsors of [REDACTED] molecules regarding their current demand and future supply outlook, so as to allow sponsors and the TGA to prepare for any potential increase in demand for [REDACTED] in the hospital setting as case number of COVID-19 increase following the easing of restrictions in various jurisdictions across Australia.

Medicines Australia requests that the information highlighted in this report be restricted from publication on the ACCC's register on public benefit grounds in accordance with our previous correspondence dated 23 September 2021, but otherwise consents to publication of this report on the register.

### Participants

The meeting was attended by representatives from the following parties:

- Therapeutic Goods Administration (TGA), including members of the Medicines Shortage Group;
- Medicines Australia;
- the Generic Biosimilar Medicines Association;
- Professor Michael Dooley of Monash University; and
- the following sponsors of [REDACTED] in Australia, being:
  - [REDACTED]
  - [REDACTED]
  - [REDACTED]
  - [REDACTED]
  - [REDACTED]

The meeting was also attended by Medicines Australia's external lawyer.

### Agenda

The following agenda items were prepared for the meeting:

- (a) Roll call – TGA
- (b) Legal statement on ACCC authorisation permitted activities – Clayton Utz
- (c) Sponsor status update (stock on hand, anticipated demand, barriers to supply, approach to supplying customers) and issues for resolution – round table with questions below for consideration
- (d) Identify gaps and opportunities for coordination - potential outcomes
- (e) Actions / next steps

### Outcomes / Next Steps

Based on current modelling, available stock and future orders, participants in the meeting identified potential future shortages of two [REDACTED] and [REDACTED]).

To manage any potential shortages of [REDACTED], the following next steps were proposed:

- the TGA to develop with Professor Michael Dooley appropriate communications to relevant stakeholders about the possibility of challenges to the supply of certain [REDACTED] and the strategies to manage any possible shortage, including by switching between [REDACTED], where appropriate for the clinical setting; and
- sponsors to consider making an application pursuant to s 19A of the Therapeutic Goods Act to import or supply substitute medicines if deemed appropriate.

[REDACTED] also identified an inability to supply [REDACTED] between May and October 2022 and has requested [REDACTED] to confirm to the TGA whether it will be able to increase its supply of [REDACTED] during that period, in order to meet hospital demand. [REDACTED] will confirm this directly to the TGA.

Medicines Australia will provide the ACCC with a copy of the minutes for the meeting as soon as practicable.

Medicines Australia's next update will cover the period of 2 October 2021 to 30 October 2021, and be a report made under the terms of interim authorisation granted to MA on 29 September 2021.

This response was drafted by Medicines Australia in consultation with [REDACTED], CEO of Generic and Biosimilar Medicines Association.

Yours sincerely,

[REDACTED]

[REDACTED]

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Medicines Australia

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The banner features the Medicines Australia logo on the left, followed by the text "New Members Only Portal" and "Register Here!" in large, bold letters. On the right, there is a photograph of a woman in a white lab coat looking through a microscope, with several colorful geometric shapes (hexagons and triangles) overlaid on the image.



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