

TGA meeting report

24 May 2022

Attendance: Therapeutic Goods Association (TGA); Medicines Australia; Generic Biosimilar Medicines Association; [REDACTED]

From: [REDACTED] Clayton Utz.
Medicines Australia

Report of meeting convened by TGA under Authorisation AA1000579 dated 8 December 2021, held 17 May 2022 (in person and virtual) (Meeting)

Introduction

1. On 8 December 2021, the ACCC issued a final determination granting conditional re-authorisation to Medicines Australia (MA) to engage in the Conduct¹ for the sole purpose of ensuring the supply of critical medicines and critical devices in response to issues arising from the COVID-19 pandemic (**Re-Authorisation**).
2. The conditions to Re-Authorisation require MA to provide a report to the ACCC within 5 business days of any meeting between MA/GBMA Working Group members in relation to the Conduct.² This report is prepared to satisfy this condition.

Report of Meeting

3. Recommendations (condition 1(a) to Re-Authorisation)

- 3.1 No material recommendations were made, or are to be made, to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Conduct.

4. Attendees at the Meeting (condition 1(b)(i) to Re-Authorisation)

- 4.1 The Meeting was convened by the TGA.
- 4.2 Representatives of the following sponsors attended the Meeting, in addition to representatives of MA (including its external legal counsel) and GBMA:

- (a) [REDACTED]
- (b) [REDACTED]; and
- (c) [REDACTED].

- 4.3 Each of the attendees at the meeting are sponsors of [REDACTED] in adults and children.

5. Agenda (condition 1(b)(ii) to Re-Authorisation)

¹ See paragraphs 1.7 and 1.8 of the Re-Authorisation for a description of the conduct which is authorised. See paragraphs 5.3 to 5.5 of the Re-Authorisation for the conditions to Re-Authorisation.

² See paragraph 5.4 of the Re-Authorisation.

- 5.1 The TGA convened the Meeting because there is a current global shortage of [REDACTED]
- 5.2 The purpose of the meeting was to enable the TGA to understand each sponsor's supply status for the product and whether there is a need for sponsors to coordinate their supply in order to meet product shortages in Australia, within the scope of the Re-Authorisation.
- 5.3 The below agenda was issued ahead of the Meeting, and used to guide the discussion:
1. *Roll call – TGA*
 2. *Legal statement on ACCC authorisation permitted activities - Clayton Utz*
 3. *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:*
 - (a) *What measures do you have in place to constrain stock and ensure equitable distribution?*
 - (b) *Is a coordinated approach to supply constraints required at this time?*
 - (c) *Can you source additional supply of your product to support potential significant increases to demand?*
 - (i) *How easily the orders can be brought forward?*
 - (ii) *What is the estimated timeframe to bring in any additional stock? Are there any barriers to a timely response?*
 - (iii) *What percentage of increase in demand could you support?*
 4. *Identify gaps and opportunities for coordination*
 5. *Actions/outcomes*

6. **Minutes (condition 1(b)(iii) to Re-Authorisation)**

- 6.1 This monthly Report comprises the Minutes.
- 6.2 The TGA noted that it has been engaging with the [REDACTED] to prepare a statement in respect of prioritisation of clinical use of the product and measures to conserve stock. The TGA has also been working with State and Territory health authorities to assist with determining where available stock is needed.

7. **Topics discussed at the Meeting (condition 1(b)(iv) to Re-Authorisation)**

- 7.1 Sponsors provided the following information in response to the Agenda:

- [REDACTED]:
- (a) [REDACTED] has taken action to actively monitor orders and prioritise distribution of its product in a fair and equitable way, but has challenges in determining which

orders should be prioritised. [REDACTED] cited that engagement with State and Territory health authorities may assist in prioritising distribution of the product.

- (b) [REDACTED] has taken measures to increase production and streamline distribution (e.g. air freight) of the product.
- (c) [REDACTED] is unable to provide any accurate information as to when its supply output will return to normal because the extent and duration of the [REDACTED] [REDACTED] is not known.
- (d) [REDACTED] did not think that coordinated action between suppliers would resolve the challenges of prioritising distribution of product.

[REDACTED]

- (e) [REDACTED] has taken action to actively monitor orders and manually allocate stock. It has prioritised public hospitals ahead of private hospitals, but has had regard to the shared public/private role that private hospitals play in rural areas.
- (f) [REDACTED] has also taken steps to streamline distribution and is working with the TGA to obtain alternative supply of the product into Australia. [REDACTED] is unable to say when its inventory will increase. Any additional supply it is able to obtain is likely to be consumed by backorders of its product.

[REDACTED]

- (g) [REDACTED] has experienced a material increase in demand for its products in the last two to four weeks and expects its stock to become low shortly.
- (h) [REDACTED] also cited global supply issues as a factor relevant to its ability to increase supply of the products in Australia.
- (i) [REDACTED] does not have visibility of where stock on hand is located and agreed that engagement with State and Territory health authorities will assist in prioritising distribution of product in Australia.
- (j) [REDACTED] expects to lodge applications with the TGA for alternative supply arrangements in the near future.
- (k) [REDACTED] suggested that the [REDACTED] should also be included in such coordinated activities.

8. MA/GBMA working group (condition 1(c) to Re-Authorisation)

- 8.1 Prior to the Meeting, MA notified the ACCC that two of the attendees invited by the TGA to attend the Meeting - namely [REDACTED] and [REDACTED] - would be added as MA/GBMA members.

9. Actions / Outcomes

- 9.1 No material decision or agreement between any of the attendees was made during the Meeting.
- 9.2 However, the TGA undertook to:
 - (a) reach out to the [REDACTED] for their views and coordination;

- (b) seek to reconvene sponsors at about the time that the [REDACTED] is anticipated to end (about 5 weeks);
- (c) facilitate any introductions between sponsors and the State and Territory health authorities, as requested; and
- (d) keep sponsors informed.