

TGA meeting report

24 May 2022

Attendance: Therapeutic Good Association (TGA); Medicines Australia; Generic Biosimilar

Medicines Association:

Clayton Utz.

From: 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

- On 8 December 2021, the ACCC issued a final determination granting conditional reauthorisation 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).
- 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

- 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.
- 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)
 - (b) ; and
 - (c)
- 4.3 Each of the attendees at the meeting are sponsors of

in adults and children.

Agenda (condition 1(b)(ii) to Re-Authoris ation)

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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.

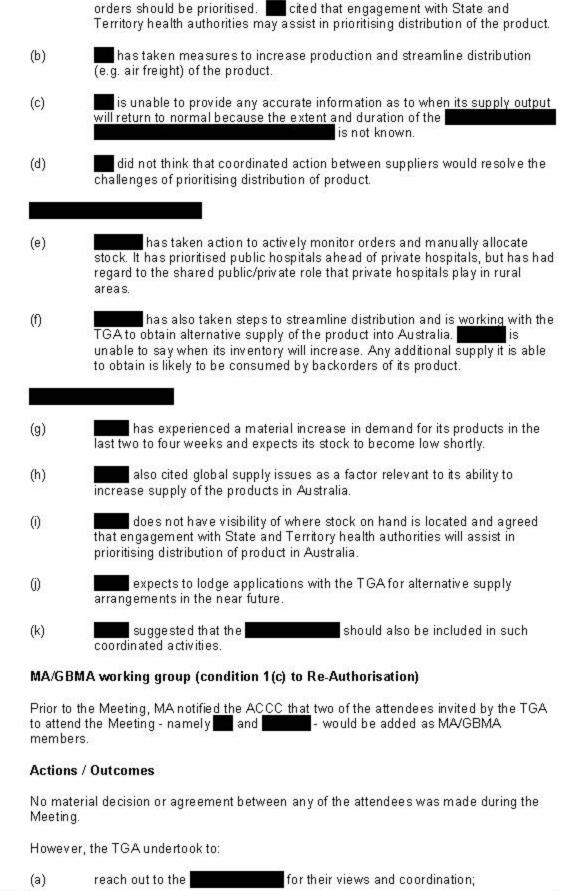
² See paragraph 5.4 of the Re-Authorisation.



- 5.1 The TGA convened the Meeting because there is a current global shortage of
- 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 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.
- Topics discussed at the Meeting (condition 1(b)(iv) to Re-Authorisation)
- 7.1 Sponsors provided the following information in response to the Agenda:
 - (a) 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

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(b) seek to reconvene sponsors at about the time that the 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.

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