TGA meeting report

23 June 2022

Attendance: Therapeutic Good Association (**TGA**); Medicines Australia; Generic Biosimilar Medicines Association (**GBMA**); [redacted] Clayton Utz.

From: **Medicines Australia**

Report of meeting convened by TGA under Authorisation AA1000579 dated 8 December 2021, **held 16 June 2022 (in person and virtual)**

Introduction

1. On 8 December 2021, the ACCC issued a final determination granting conditional re-authorisation to Medicines Australia (**MA**) to engage in the Conduct[1] 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. On 17 May 2022, the TGA called for a meeting between MA/GBMA Working Group Members responsible for the supply of [redacted] (**Product**) pursuant to the Re-Authorisation.

3. On 16 June 2022, the TGA requested a further meeting between the TGA and attendees from the meeting held on 17 May 2022 (**June Meeting**).

4. 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

5. **Recommendations (condition 1(a) to Re-Authorisation)**

5.1 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.

6. **Attendees at the June Meeting (condition 1(b)(i) to Re-Authorisation)**

6.1 The June Meeting was convened by the TGA.

6.2 Representatives of the following sponsors attended the June Meeting, in addition to representatives of MA (including its external legal counsel) and GBMA:

(a) [redacted];

(b) [redacted]; and

(c) [redacted].

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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.

6.3 Each of the attendees at the June Meeting are sponsors of [redacted] in adults and children.

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

7.1 The TGA convened the June Meeting because there is a current ongoing global shortage of [redacted].

7.2 The purpose of the June 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.

7.3 Ahead of the Meeting, the TGA provided the following main aims for the June Meeting:

(a) *To get an understanding of the likely duration of the shortages;*

(b) *To get information on the current supply situation in the market of ARTG and non-ARTG products. There are a few overseas registered products approved for supply under section 19A of the TG Act, and it would be helpful to get an understanding of how much of the proportion of a sponsors usual demand is covered, to ascertain if there are still gaps in supply;*

(c) *An opportunity for sponsors to provide relevant updates - it's been three weeks since the previous meeting and timely for everyone to meet again.*

7.4 The June Meeting was conducted under the following structure, which was based on the meeting of 17 May 2022:

1. Roll call – TGA

2. Legal statement on ACCC authorisation permitted activities - Clayton Utz

3. Update provided by TGA

4. Sponsor status update (stock on hand, anticipated demand, barriers to supply) and issues for resolution – round table input by all sponsors

5. Actions/outcomes

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

8.1 This monthly Report comprises the Minutes.

8.2 The TGA:

(a) noted that it has been engaging with State and Territory Health Departments which have issued safety alerts and protocol changes regarding the use of the Product. State and Territory Health Departments have also reported to the TGA that the heightened level of demand for the Product has slowed to some extent, and that this may indicate that Product conservation measures (by the State and Territory Health Departments) are working;

(b) noted that it has been in contact with the Department of Infrastructure to put it on notice that sponsors may raise issues regarding freight / transportation as well as bringing in alternative therapies under section 19A approvals of the Therapeutic Goods Act; and

(c) has engaged with the Australasian College of Emergency Doctors for the purpose of developing an updated statement in respect of potential changes to protocols used during diagnosis that involve the Product.

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

9.1 Sponsors provided the following status updates:

[redacted]:

(a) [redacted] considers that the supply of the Product appears to be more positive compared to the last TGA meeting (about 4 weeks ago). [redacted] factory located in Shanghai is fully operational and [redacted] has been able to bring in more Product to Australia that would normally be the case for this time of year. [redacted] has not experienced as many logistical complications as expected and anticipates that it will be able to continue importing Product into Australia.

(b) [redacted] noted that it is focussing on the production and distribution of 4 variants of the Product which are most used or essential to the market and that production of the remaining 12 variants has been and continues to be affected. [redacted] is unable to state when the availability of the remaining 12 variants of the Product will improve (but is seeing some easing of supply restrictions already).

(c) [redacted] has commenced bringing in stock under section 19A approvals but considers this to be a temporary measure. [redacted] intends to remove the supply shortage notifications on the TGA website for the 4 variants of the Product currently available but is unable to specify a date for the removal of the 12 remaining supply shortage notifications.

(d) [redacted] considers shipping to be reliable. [redacted] has observed an increase in demand resulting from customers building a buffer of stock. [redacted] declined to share buffer stock demand levels.

[redacted]:

(e) [redacted] is experiencing constrained stock on hand because of being unable to support market demand (which has been 15-20 times higher than normal). [redacted] is still manually allocating stock to address areas of critical need.

(f) [redacted] is relying on being able to import stock into Australia under a section 19A approvals. It is considering further section 19A applications, depending on the outlook over the next 1-3 months. However, [redacted] said that there is a risk of obsolescence of stock brought into Australia under section 19A approvals because of the regulatory time limit for use. [redacted] queried whether there could be an extension of the regulatory time limit in these circumstances.

(g) The TGA responded that it recognises that markets tend to remain disrupted after shortages are resolved and that it was taking a conservative approach. The TGA noted that there appears to be an increased demand due to customers acquiring buffer stock. The TGA undertook to continue to engage with [redacted] to get a clearer sense of dates of supply for all variants and the period of any shortages to determine whether the time limit of any section 19A approvals need extending.

(h) [redacted] has received feedback from customers that public health departments have imposed alternative modalities and used lower levels of Product where possible. [redacted] understands that private clinics have reported shortages of Product because supply to the public system is being prioritised.

(i) [redacted] stated that its supply issues relate to an inability to scale up product quickly when already at capacity, rather than any distribution / supply chain challenges.

[redacted]

(j) [redacted] continues to manually allocate stock and has supplied some Product under a section 19A approvals.

(k) [redacted] has observed that State and Territory Health Departments appear to be taking control of stock and distributing that stock to hospitals in need, which is creating further delay. However, in the last week, [redacted] has observed less demand intensity and believes this is from an apparent increase in stock availability.

10. **Actions / Outcomes**

10.1 No material decision or agreement between any of the attendees was made during the June Meeting.

10.2 However, the TGA undertook to:

(a) engage with [redacted] to clarify periods of shortage and to provide an update to sponsors in due course; and

(b) seek to reconvene sponsors once further information about any shortage period is known.