File Note

Matter name:	Medicines Australia application for revocation and substitution		
ACCC parties	Gavin Jones, David Hatfield, Sophie Mitchell, Tom Lyle, Gemma Smith		
TRACKIT No	AA1000579		
Other parties	Therapeutic Goods Administration (**TGA**): • Elspeth Kay (Assistant Secretary – Pharmacovigilance & Special Access) • Cath Brown (Director – Medicine Shortages)		
Time:	10:30 AEDT	**Date:**	8 October 2021
Phone to ☐	**Phone from** ☐	**Meeting** ☒	**Other** ☐

The ACCC met with the TGA on 8 October 2021 to discuss Medicines Australia's application for revocation of authorisation AA1000486 and substitution of authorisation AA1000579. The TGA made the following points:

Effectiveness of the previous authorisation and ongoing need

1. The Medicines Australia (**MA**) authorisation has been used sparingly. There was a period last year and earlier this year when it didn't need to be used but more recently it has started to be used again. It has been really useful in cases where there have been demand spikes for certain medicines that are pandemic related such as the supply of certain ICU medicines. For example, because COVID-19 cases may rise with plans to open up around the country, there may be increased demand for neuromuscular blockers that extend across a range of sponsors and molecules. Getting the sponsors in a room to discuss stock levels and plan for anticipated demand and possible resolutions to issues is useful.
2. Actions coming out of the last meeting included decisions such as communicating back to states and territories about the supply picture and informing them that it would be prudent for them to provide guidance to clinicians about switching between certain products so patients get the medicines they need.
3. Sponsors have not taken coordinated actions under the authorisation, but the ability to share information has allowed the TGA to take actions and communicate with the sector about supply.
4. The conduct under the previous authorisation worked as expected. Having the TGA as the trigger the meetings is good as it gives the sponsors and MA comfort that they are abiding by the authorisation and they are only meeting when there is a perceived need or an issue to be worked through.

Benefits and detriments under the previous authorisation

5. No detriments come to mind but the benefits have been that the sharing of information has assisted sponsors to undertake individual actions around ensuring there are no gaps in supply.

Conduct going forward and period of authorisation

6. Under the current interim authorisation and the final authorisation, if granted, the TGA expects they will convene more meetings compared to the frequency under the previous authorisation. This is due to the expectation that as states ease COVID-19 restrictions and open up, there may be a need to meet to discuss ICU medicines in response to an increase in patients and any potential supply issues.
7. The main use of the authorisation will be to work alongside the states' plans for opening up. It is not clear how far into 2022 that will continue to be a big issue so it is hard to say what the appropriate period of re-authorisation is. Lockdowns have been keeping cases down and therefore the need for coordinated action to manage supply at bay but it is reassuring to have this as a tool available to us.

On this call, the ACCC and TGA also discussed the National Pharmaceutical Services Association application for revocation and substitution. A record of that conversation can be found at https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/national-pharmaceutical-services-association-npsa-0.

Call ended at approximately 11:00 AM AEDT